Exhibit 80

COPY

Schering Laboratories Generic Strategy
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Schering Laboratories Generic Strategy
Executive Summary

Overview

The growing emphasis on health care cost containment and the resultant expansion of the Managed Care sector coupled with the increased utilization of generics, poses a long-term threat for Schering Laboratories. In addition, in this environment the loss of patent protection for several major Labs products (most notably Proventil Inhaler) will require innovative strategies to maximize the brands profit potential.

The changes occurring in the marketplace are historic in scope. Cost containment pressures by the government, Managed Care providers and Third Party insurers have led to increased use of generics and sometimes mandated therapeutic substitution where lower-cost drug alternatives exist. The dispensing decision is moving away from the physician, where it is based on the risk/benefit of the therapy to the patient, towards many other third parties, where cost is the primary determinant. The evolution of generic and therapeutic substitution will pose a significant threat to those products with multi-source competition. In addition, this marketplace will require demonstrated pharmacoeconomic value for current and future pharmaceutical products. Research and development-based pharmaceutical companies must be prepared to defend in-line products in this environment.

There have been many changes in the pharmaceutical industry since our last examination of the generic issue. The generic segment of the market has become an integral part of the industry with sales totalling $3 billion in 1992 and growing. The outcome of the generic scandal served to strengthen the generic segment as the marginal players were shaken out and the quality firms remained. Generic drug firms can no longer be viewed as simply price cutters that knock off copies of our products. Players in this market are increasingly becoming complete companies with focused strategies and original products of their own (e.g., Mylan and Copley) and should be viewed as significant competitors. Many of those who are currently running the generic companies came from the PMA side of the business. Additionally, PMA companies have been involved in the generic segment of the industry for many years. The initial involvement of PMA companies was in the form of subsidiaries. The most well known are Ciba-Geigy's wholly owned subsidiary Geveva, Warner-Lambert's Warner-Chilcott and American-Cyanamid's Lederle Standard Products. It is a recent trend for PMA

companies to get involved in the generic segment as a defensive strategy for their own products. Examples of strategic alliances include SmithKline Beecham and Rugby (Dyazide) and Marion Merrell Dow and Rugby (Cardizem). ICI and Merck established dedicated "boutique" divisions, namely, IPR and West Point Pharma. IPR currently carries only two products, Tenormin and Tenoretic, while West Point Pharma recently announced the addition of ten products to its current one-line product, Dolobid.

Recommendation

To successfully protect against the inevitable sales and share erosion of our branded products and to leverage up our branded products in the Managed Care environment, it is recommended that Schering Laboratories establish a position in the generic marketplace. The strategy necessary to achieve entry focuses on the following objectives:

- Protect and extend the life cycle of our branded products as patents expire.
- Seek to create leverage for our Managed Care business with value added generics.
- Provide Schering with an effective defensive position to protect our multi-source portfolio from generic and therapeutic substitution.

Action Plan

- Expand Warrick Pharmaceuticals as a separate entity to function as the vehicle to market "generic" versions of our current off-patent, non-promoted products. This tactic will allow us to learn and gain experience in the evolving generic marketplace. The Warrick Pharmaceuticals entity will require a staff of 15 persons and funding of $5-8 million over a 3-4 year period.

- We will continue to aggressively defend our current in-line branded products from generic competition and therapeutic substitution. We will make all preparations to implement the "first-to-market" strategy for Proventil Inhaler by introducing via the Warrick Pharmaceuticals entity a "generic" albuterol inhaler. We will wait with this strategy and only implement 60

days prior to the confirmed introduction of a generic competitor. The value of this strategy is detailed on page 53 of this Plan.

- Develop a portfolio of generic versions of current brandname patented products within the Warrick Pharmaceuticals entity. Market this portfolio to leverage value for our in-line, brandname products in the Managed Care marketplace.

After evaluation of various options to facilitate entry (i.e., acquisition, strategic alliance - See Chapter V) we recommend Schering Laboratories pursue a low cost, low investment avenue of internally developing a generic portfolio and expertise.

Protect and extend the life cycle of our branded products.

Schering Laboratories has been aggressive and successful to date in delaying or mitigating generic competition for most of our major in-line products (i.e., the Proventil Inhaler strategy, unique Repetab technology to maintain the albuterol tablet franchise, and effective Theo-Dur brand positioning). While we will continue to use every resource at our disposal to prevent generic entry, we also recognize it as inevitable. By introducing lower-priced private label (generic) versions of our own branded products, such as Proventil Inhaler, we will successfully be able to extend their life cycle and profit stream beyond the point with which we are normally familiar. Instead of allowing a branded product to simply "die out" in its generic phase, we will be full participants, capturing sales and share during that period. By having our own private label versions we will also be able to maintain, if not increase, prices on the branded version. We emphasize that the launching of our private label versions will occur only at just the right time (ideally 60-90 days prior to the first anticipated generic) and we will carefully monitor market conditions before entry (see Chapter VI for further discussion of this strategy).

Currently, we are marketing Proventil unit dose solution under a private label using the trade name "Warrick Pharmaceuticals" for the close-ended home health care market. This separate entity has been established for this specific effort but would be expanded and used as the vehicle to launch generic versions of our own products as stated above (e.g., Proventil Inhaler in 1994).

In addition, we could further enhance the profits of branded products in the near term by using the Warrick entity as a vehicle to minimize certain rebates.

Specifically under current Medicaid legislation, by establishing separate NDC codes for the same product, i.e., one for Schering and one for Warrick, we believe they would be treated as distinct products for filing purposes. Thus, we could move deep discounted business for products with minimal full price spillover into Warrick and not be forced to provide large "best price" rebates in the retail Medicaid market. We must note that these potential rebate savings would be short term in that we could expect this loophole to be closed by proposed legislative changes in the near future. We are currently assessing what specific products fit this profile and the amount of savings that may exist.

Seek to create leverage for our Managed Care business in the future.

Economic value can be offered to selected Managed Care buyers by providing them with generic products at a price significantly below their existing acquisition cost. By manufacturing and integrating generic versions of high utilization products coming off patent (e.g., Capoten) with our branded products, we can gain additional leverage for our brands by either commanding higher prices or through increased usage. Maximum leveraging value in a generic market subject to rapid price erosion, is available only to the early generic player (see page 35). It is imperative that we obtain this "first mover" advantage by being early on the market with a generic version.

We will supplement this line of "promotional" generics with private label versions of our own products. We are not, however, attempting to be a broad line generic firm. In the near term, leverage can be achieved in that segment of the Managed Care market that both purchases and dispenses the drug. The "controllable segment", i.e., staff-model, HMO's, hospitals and mail order, represents approximately 20% of the pharmaceutical distribution market at this time. We will develop contract opportunities in these close-ended markets immediately with our own line of Warrick-labeled Schering minor products. This strategy is not immediately viable in the open Managed Care markets (i.e., IPAs, PPOs, PMOs) because generics are not usually contracted for by Managed Care pharmacy management organizations. They allow chain stores and independent retailers to select the product and the Managed Care provider caps the cost via a MAC (Maximum Allowable Cost). The pharmacy then searches for the lowest price under the MAC.

In addition, point of purchase computer controls do not differentiate between generics, thus the ability to specify and control a particular generic does not

presently exist. Pharmacists submit "generic claims" to the managed provider using any of the multiple generic NDC codes.

This is in contrast to the innovator brand product's maximum allowable costs which are usually reimbursed at the AWP price minus 10% plus a $2-$3 "dispensing" fee. We currently participate at this level by gaining formulary acceptance and market share in specific systems by providing contracted discounts and "bundles."

Longer term, 3-4 years, as we acquire our ongoing stable of ANDA's, we could then use the gap between our manufacturing cost and the generic "retail" acquisition price to leverage up the price and utilization of our other branded products. By 1995 with a solid core of "promotional generics", broader retail distribution through Warrick, and the evolution of pharmacy computer point-of-purchase controls to enforce retail generic utilization, we will be positioned to impact the largest, fastest growing segment of the Managed Care market. However, with the short expected life of these promotional generics (1-3 years), we would require a steady restocking of this portfolio to truly be effective in these markets. Cost of this strategy is $5-8 million over the next 3-4 years to begin development of a strategic core of future ANDA's. These costs can be more than recovered from incremental revenues associated with managed care leverage (see Chapter VI and Appendix 1 for further discussion).

Establish an effective defensive position for Schering multi-source products.

Increased mandatory therapeutic substitution and generic competition will continue to erode our in-line multi-source business. By establishing our own operation, we will be gaining knowledge of, and creating a defensive position in this evolving marketplace. Schering's position in the generic segment will provide a new area of involvement for us and create an additional revenue stream at a low cost of entry.

Enhanced branded products

In addition, we will continue to pursue the business opportunities to make enhanced versions of products that are going off patent by applying delivery technology we currently have or may acquire (i.e., sustained-release, Repetab, Zydis technology). This business will continue to be developed within the context and structure of Schering Laboratories.

Exit Alternatives

While the above discussion addresses the advantages of getting and staying involved in this market for the long run, we will nonetheless be able to withdraw from the market if necessary. If that decision is made, we will be able to do so with a disposable asset. The Warrick name, with its stable of ANDA's and approved products, will have an asset value should we decide to dispose of them. Alternately, we may decide to allow another generic firm to sell them while we continue to manufacture them, thus keeping production efficiencies.

Summary

Schering Laboratories core mission will be to continue our heritage as a research-and-development based health care company, providing value to our shareholders and patients through the discovery and development of quality, cost-effective products. Our strategic business effort must and will remain focused on succeeding as an innovative research based pharmaceutical entity. The strategic objectives of Warrick Pharmaceuticals are to protect our branded products as patents expire, to create leverage for the managed care markets, and to defend our multi-source brands from generic competition. These objectives will not distract Schering Laboratories from its core mission.

Warrick Pharmaceuticals will be created as a free-standing entity with minimal infrastructure and will report into the President of Schering Laboratories. This subsidiary will be kept separate in order to grant the necessary autonomy to compete effectively in this marketplace.

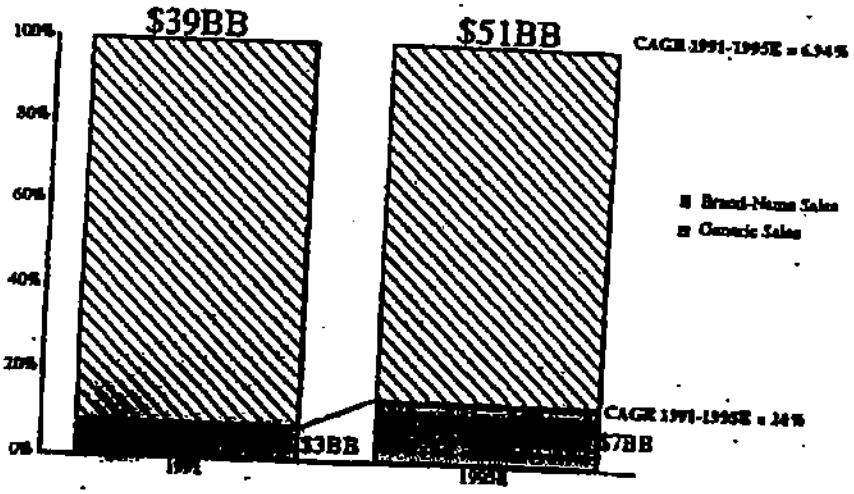
A complete discussion of the generic drug segment, its evolution and market dynamics is included in Chapters II, III and IV of this document. Further discussion of the Schering Laboratories' strategic options and approaches to accomplish the aforementioned objectives is outlined in Chapters V and VI. Additionally, the Appendix includes a detailed discussion on leveraging managed care, potential rebate implications, the Warrick portfolio of Schering minor products, and profiles of the major players in the generic industry.

Chapter I
Overview: Schering Generic Challenge

A. Background

The generic drug segment has grown rapidly over the past ten years to become a significant part of the pharmaceutical marketplace. Sales of generic drugs represented approximately $3 Billion in 1992, and it is anticipated that this segment of the market will grow at an average annual rate of 20-30% over the next several years. While the generic segment represented approximately 8% of the pharmaceutical industry in 1991, this figure is anticipated to increase to 14% by 1995.

Figure 1
United States Prescription Drug Sales
(1991-1995E)



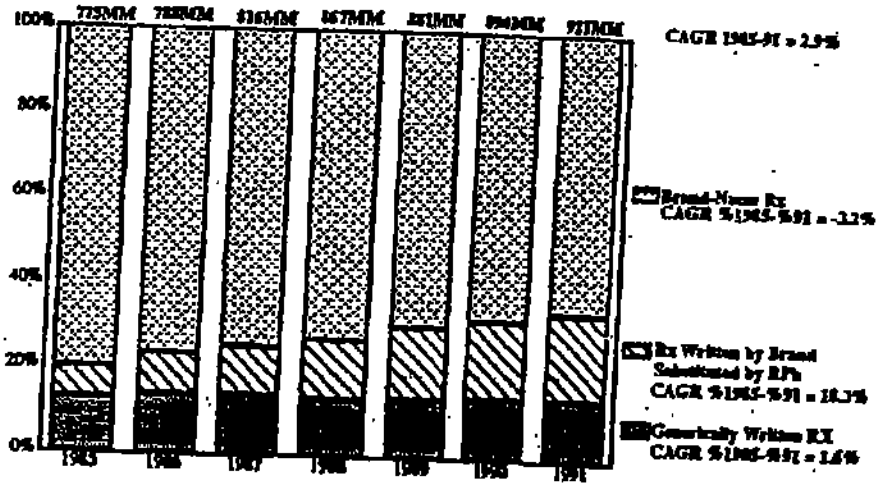
Source: Various analysts (County Nat West, Kidder Peabody)

Industry Growth

Cost containment pressures from all sides of the industry are dictating increased generic substitution. The influence of managed care, government

price controls, and third party insurers has made for greater use of generic drugs. In addition to the increased savings to third party payors, one of the realities of this market is that pharmacists often make a greater profit on a generic prescription than a branded prescription. This trend towards increased use of generics is best demonstrated in Figure 2. In 1985 generic drugs accounted for 20% of total new prescriptions filled in the United States. By 1991 this figure increased to 35%, representing an annual growth of close to 10%. It is estimated that generic drugs will account for 50% of all new prescriptions in the United States by the year 2000.

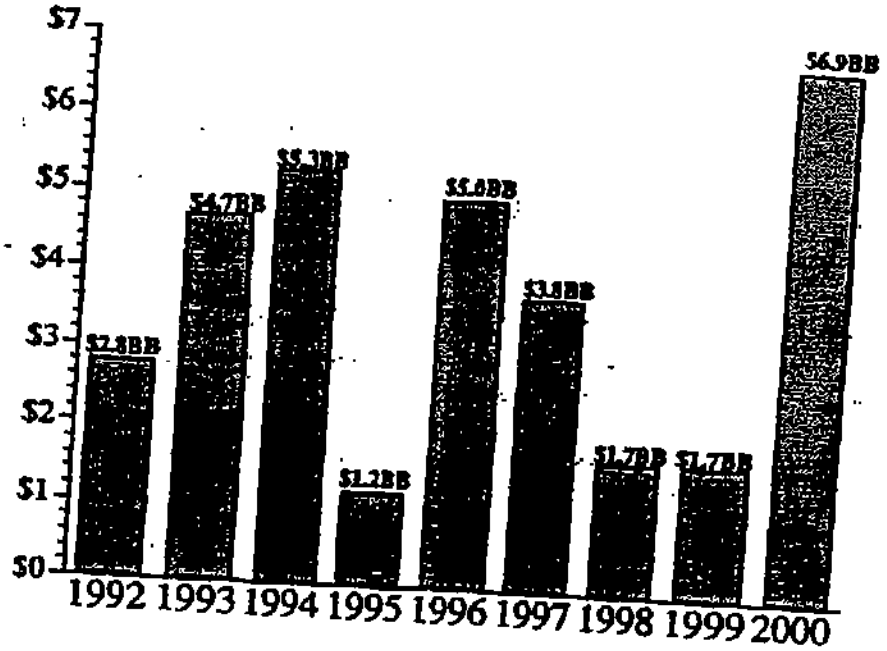
Figure 2
Breakdown of Total New Prescriptions in the United States (1985-1991)



Source: IMS

Over the next five to ten years numerous products are due to lose patent protection. Many of these are "blockbuster" drugs which present great opportunity to the generic segment. It is estimated that over the next five years, the market value of drugs losing patent protection will exceed $19BB. While this figure represents the branded sales of those drugs, applying current generic penetration trends of 50% and an average price discount of 55%, that translates into an estimated $4.3 Billion of generic sales. Figure 3 shows the estimated market value of branded drugs losing patent protection in each respective year.

Figure 3
Brand Name Drug Sales Losing Patent Protection
(1992-1996-Year ending June 30th)



Source: Analysts estimates (County Nat West, Kidder Peabody)

A listing of the major drugs that will be coming off patent at the end of 1993 through 1998 is included in Appendix 5. As the table indicates these products treat a wide array of conditions ranging from allergies to cancer.

Just as other major brand name pharmaceutical companies will be witnessing the loss of patent protection on their major brands, we will also be losing patent protection on several of our products.

[redacted]	Table 1 Year Off Patent	1992 Sales
Proventil (inhaler)	Off (1989)	$228MM
Normodyne	1998	$52MM
Lotrisone	1998	$82MM
Vanceril	1999	$58MM

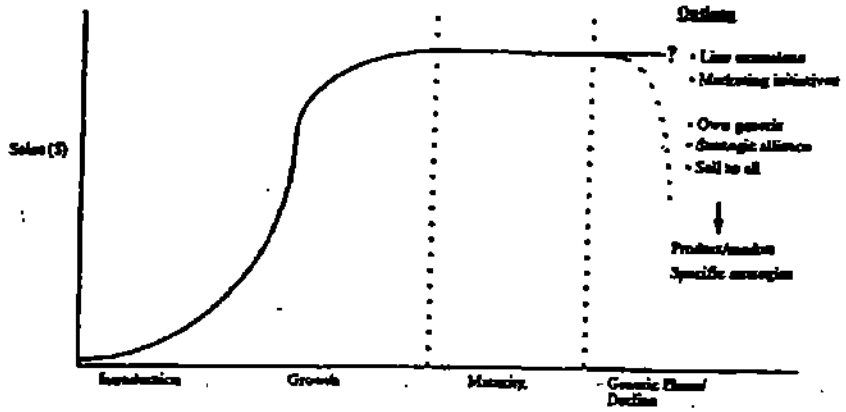
Schering Generic Challenge

Generic drugs and drug companies have been traditionally viewed with a disdainful eye by PMA companies. There has been a feeling that these companies were given an unfair advantage at our expense and that they were ruthless price cutters, an anathema to our industry.

The challenge for us is to view the generic market segment as it is today and as it is evolving. The generic scandal shook out many marginal players. Those who remain are stronger, leaner and more competent competitors. Many research based companies have had executives leave to take on positions at generic drug firms. While this has been common throughout the industry, it is particularly well demonstrated by the backgrounds of the current key executives at Schein Pharmaceutical (see Appendix 4 on Schein Pharmaceuticals). These companies strive to produce high quality products while remaining highly competitive in a price sensitive marketplace.

The data and the trends paint a clear picture of rapid growth in the generic segment of our industry. The rate of generic substitution will also continue to grow. Our challenge on a macro basis is to view generics as just another segment of our industry in which we are able to compete. On a micro basis we must begin to view the generic phase as a natural part of a product's life cycle. It is a phase to be delayed as long as possible, but it is a phase which will come eventually and one which we as innovators should profit from. Figure 4 demonstrates this new way to view the extended "generic" phase of a product's life cycle.

Figure 4
A New Life Cycle Paradigm



B. Objectives

In entering the generic segment of the pharmaceutical industry we must stay clearly focused on our objectives:

Protect and extend the life cycle of our branded products.

Brand management has been aggressive and successful to date in delaying generic competition for our branded products. While we will continue to use every resource at our disposal to prevent generic entry we also recognize that it is inevitable. By introducing generic versions of our own branded products we will successfully be able to extend their life cycle beyond the point with which we are normally familiar. Instead of allowing a branded product to simply "die out" in its generic phase we will be full participants, capturing sales and share during that period. By having our own generic versions we will also be able to maintain, if not increase, prices on the branded version. The launching of our generic versions will occur only at just the right time (ideally 60-90 days prior to the first anticipated generic firm).

Seek to create leverage for our managed care business in the future.

In addition to generic versions of our own products we will be creating a line of "promotional" generics which will be used to fill out a product portfolio

for Wa[redacted] By establishing a full line of generic products we should be able to [redacted] leverage with managed care in the future. Our ability to bundle our line of generics with our branded products in managed care will allow us to offer value to the customer without reducing prices on our more profitable items. Since only 20% of the pharmaceutical distribution market can be considered "controllable" at this time, and because we will need 2-3 years to establish a complete line of generics, this must be viewed as a long-term objective.

Establish an effective defensive position for Schering Laboratories multi-source products.

Increased mandatory therapeutic substitution as well as generic competition will continue to erode our in-line multi-source business. By establishing our own operation, we will be gaining knowledge of, and creating a defensive position in this evolving marketplace. Schering's position in the generic segment will provide a new area of involvement for us and create an additional revenue stream at a low cost of entry.

Chapter II
The Generic Drug Segment

A. Background

Generic drugs have been in existence since the early part of the 20th century, but the industry as a whole did not come into prominence until the 1980's. In 1962, with the passing of the Kefauver-Harris amendments, all drugs (including generics) were required to go through the entire NDA process to demonstrate safety and efficacy to the FDA. In 1981 opportunities increased for generic drug firms, as the FDA began accepting "paper" NDA's, which allowed generic manufacturers to receive approval by submitting published reports that demonstrated the necessary safety, efficacy, and bioequivalency requirements for their products.

It was not until 1984, with the passing of the Waxman-Hatch Act, that the generic drug industry firmly established itself in the pharmaceutical marketplace. As part of the Waxman-Hatch Act, the Abbreviated New Drug Application (ANDA) was created. The ANDA process waives the requirement of conducting complete clinical studies, but requires bioavailability and bioequivalence studies. "Bioavailability" indicates the rate and extent of absorption and levels of concentration of a drug in the blood stream needed to produce a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and the levels of concentration of a generic drug in the body are substantially equivalent to those of the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of an approved drug. Before the Waxman-Hatch Act, the generic drug manufacturers had to duplicate the extensive clinical trials the innovator drug company originally performed for approval of the brand-name drug. The high cost of these trials created a barrier to entry that limited the introduction of generic drugs once innovators' products went off patent. The reduced time and cost required to bring a generic to market increased the generic penetration of the US drug market.

The Waxman-Hatch Act also stimulated innovator company research and development, by allowing patent extensions for a portion of the time the drug was at the FDA under review. It also established a three year patent extension for new dosage forms and new indications on older products.

The ANDA Process

There are two ways to acquire ANDA's on generic products. The most obvious course is to file all of the necessary papers with the FDA and pass all the bioequivalence tests as laid out by the FDA. This process takes an average of 18-24 months, from start to finish, for an "average" drug, longer for a "complex" drug (complexity of demonstrating bioequivalence). In general, the time frame for ANDA development and registration can be compressed for compounds that are highly-soluable or highly-permiable, e.g. many immediate release products. Conversely, the time frame for ANDA development is typically longer for poorly-soluable products, e.g. most sustained-release compounds. Alternatively, a company can purchase an ANDA from another company or buy a company that has ANDA's, thus permitting more rapid manufacturing of generics, because the purchaser can forego the bioequivalence testing requirements. The cost of filing for a new ANDA is estimated to be around $350,000 for an "average drug" and up to $1 Million for a complex drug. The large majority of the cost comes from the bioequivalence studies, which involve one human crossover study and one food interaction study (which may need to be repeated). 100,000 units of the drug must be manufactured for the FDA to use in the bioequivalency testing phase alone, accounting for another significant portion of the cost.

One problem that firms face when purchasing an ANDA is in duplicating the manufacturing facilities and processes. The approval is contingent on exact duplication of the manufacturing process that was originally approved by the FDA, using the very same manufacturing equipment. Even though techniques and equipment may be outdated, the purchasing company can not alter the previous ANDA holders technology for manufacturing the generic. The equipment must be physically transferred to a new location or the entire facility must be bought. In some cases, this may actually be more costly and require more time than filing for one's own ANDA. After the manufacturing technology is transferred, 2 batches of the product must be produced and a short stability program (3 months) must be conducted. Following this program, an equivalency study that compares the original ANDA product with your manufactured version should be conducted and submitted in a product equivalency report. The conclusion that can be drawn is only limited time savings are achieved when ANDA's are purchased.

Also, at the present time, innovators need only acquire a new NDC number for the generic version of their own brand-name product in order to begin marketing and distributing that product generically.

Typically an "enhanced" or "advantaged" drug requires approval through the full NDA process. However, a company is allowed to file a "petition" on an approved drug (either an NDA or an ANDA drug) if it is enhanced under one of the following four criteria: a change in dosage form (i.e. from tablet to capsule), a change in strength (i.e. from 50mg to 75mg), a new route of administration (ex. delivery change from injection to oral), a change in two or more active ingredients (substituting compounds from the same chemical class).

The Generic Scandal

The generics industry has only recently begun to recover from a scandal that occurred in the late 1980s. In the summer of 1988, on a tip from Mylan, a Congressional inquiry headed by Congressman Dingell uncovered bribery of FDA officials and fraud in ANDA applications. Several generic manufacturers had been successfully manipulating the ANDA approval process to their benefit. The discovery was made that some firms were submitting brand-name products for their bioequivalence tests, while others paid FDA officials to speed up the approval process for their ANDA applications. Eight manufacturers, twenty seven executives and five FDA officials were convicted of various crimes. Many generic prescription drugs were pulled from pharmacy shelves, even though none of the drugs were shown to have directly harmed anyone. This scandal forced several manufacturers off the market and caused the FDA ANDA approval process to grind to a halt as the FDA cleaned its house. The image and reputation of the generic industry was tarnished by this scandal. This scandal fueled the doubt in the minds of everyone about the quality and safety of generic products. However, current growth of the generic market may prove that the long term implications will be minimal. While growth was restricted for a few years, the industry looks to be quickly recovering with increased generic substitution (indicating a renewed faith in generics).

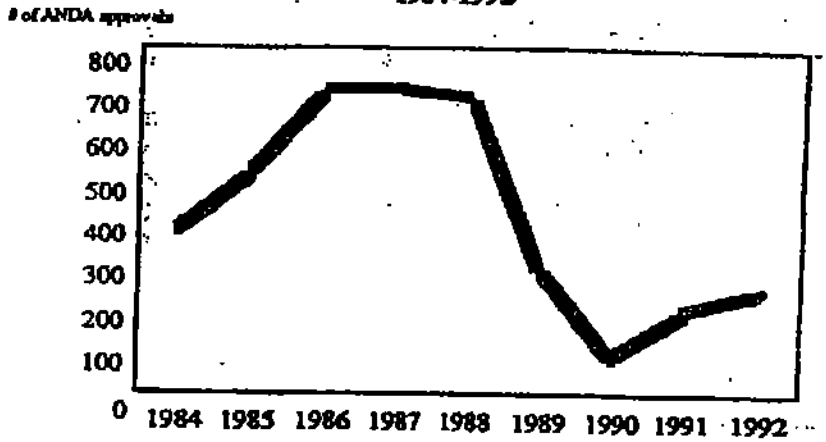
Continuing Growth

The outlook for the generic industry and for the firms that survived the scandal is optimistic. There are several factors that currently exist that will contribute to growth within the industry over the next five to ten years. The major growth factors are as follows: a tremendous number of products coming off patent in the next five to ten years (approximately 100 products over the next several years); encouragement of generic substitution (increasing consumer and corporate concern about health-care costs, the growth of managed care, and government concerns about the budget, all of

which has focused attention on the price of branded drugs); and fewer players in the market.

It is estimated that between 1992 and 1996 the market value of drugs going off patent will exceed $19 Billion. In 1992, some 60 percent of the 200 best selling prescription drugs were available in generic form. By 1995, 94 percent of the 1992 list will be available generically. Of the products scheduled to come off patent, some of the more notable ones include Naprosyn, Tagamet, Seldane and Zantac. Not only are there a substantial number of products coming off patent, but the FDA is once again approving generics in larger numbers since the scandal, as evidenced in Figure 5.

Figure 5
FDA ANDA Approvals
1984-1992

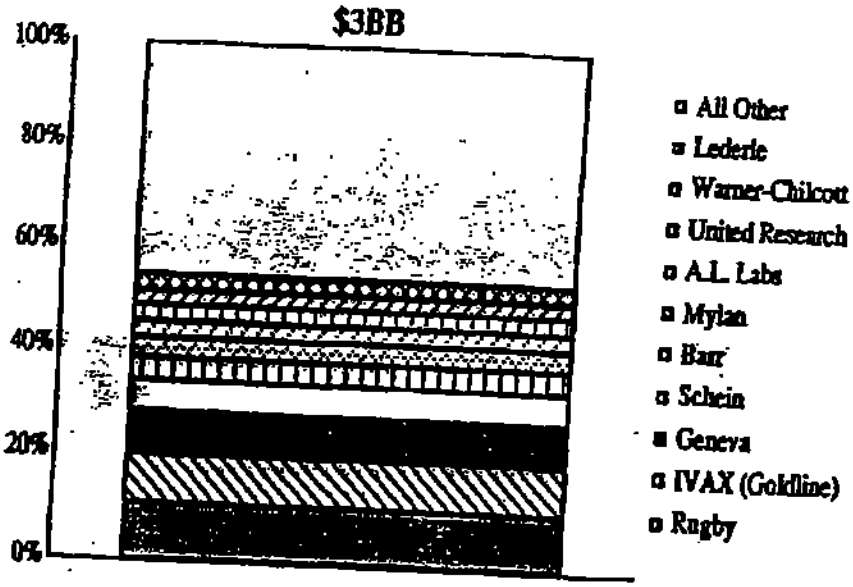


Source: FDA

President Clinton's health care reform plan could provide a boost to generic sales as managed health care organizations and insurance companies will be increasingly in control of patient formularies. The Federal government now mandates state Medicaid programs to require pharmacies to dispense generics at all times except when a doctor specifies "brand medically necessary." If states do not comply, they stand to lose federal matching funds. With the ever increasing cost of health care in the United States, consumers, corporations, insurers and third party payors will turn to generic products.

It is argued that since the scandal, the industry has emerged stronger as consolidation among the survivors has occurred. This consolidation of market share is increasingly occurring through acquisition and withdrawal of marginal firms. Currently, the top ten generic companies account for 50% of all generic sales (see Figure 6). To be certain, the companies that can remain clear of FDA regulatory investigations and problems will most likely succeed, while those that have recurrent problems at the FDA will fail. The large companies that are well positioned and firmly entrenched in the marketplace will continue to thrive. In addition, the increasing concentration of buying power among the HMOs, GPOs, chain drug stores, wholesalers and independent pharmacy buying groups facilitates generic substitution. They are able to position their buying power to leverage lower prices on products and if they do not receive the lowest price they may switch to a generic substitute. In addition, it is now possible for these groups to acquire a large portion of their needs from one supplier, reducing the need for smaller players.

Figure 6
Generic Pharmaceutical Industry Sales Breakdown

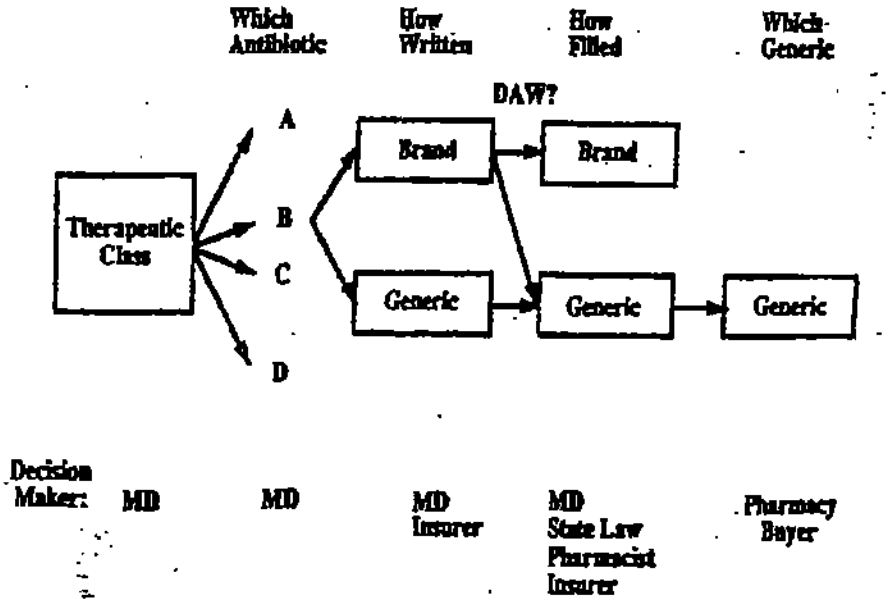


Source: Analysts(County Nat West, Kidder Peabody)

Who is the Customer?

While Pfizer companies are used to detailing physicians with large in-person sales forces to sell their product, these efforts would be futile in the generic marketplace. The decision makers are no longer the physicians, but rather the pharmacists, the wholesalers, the personnel at large chain pharmacies, the insurers, and the government. Figure 7 demonstrates the inherent differences in the channels of the generic marketplace versus that of the branded.

Figure 7
Decision Making Power in the Brand and Generic Segments of the Pharmaceutical Industry

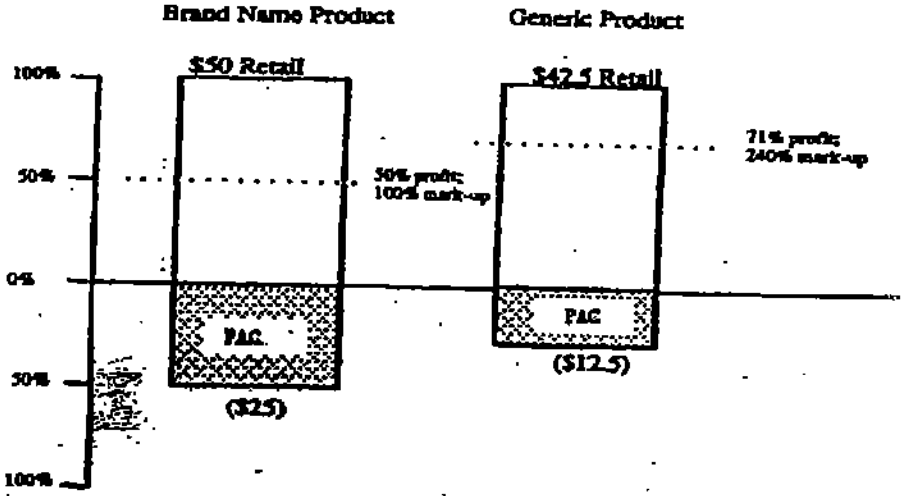


Generic substitution has been increasing rapidly and is expected to continue to do so in the future. As managed care organizations increase in popularity and cost containment pressure forces many such organizations to use restricted formularies the use of generics will rise. Kaiser Permanente, the largest managed care organization in the country, utilizes a closed and restricted formulary, whereby they will only stock one generic in any given

product group. More and more, managed care groups are facing cost containment pressures.

On another level, generic substitution is increasing significantly at the pharmacies. Third party payors, insurers and drug benefit programs are requiring more patients to have prescriptions filled with generic alternatives to help defray costs. Not only is this beneficial to the patient and third party payors, but it is also beneficial to the pharmacies. As mentioned earlier, one of the ironic realities of the generic marketplace is that a pharmacy can earn a higher profit by filling a prescription with a generic than with the branded product. On an absolute dollar basis, the difference between the margins from generics and brand-name drugs is not as great, due to the brand-name drug's higher price, but the generics overall margins are still better. Thus, pharmacists are encouraging generic substitution wherever possible because it directly bolsters their bottom lines. (Refer to Figure 8)

Figure 8
Pharmacy Pricing - Brand Name vs. Generic Products



PAC = Pharmacy Aquisition Cost

B. Structure

The generic segment of the pharmaceutical industry is comprised of over 200 players, a few of which can be considered "powerhouses" (refer to Figure 6). It is possible to characterize the different types of generic companies into five major categories: the manufacturer, the distributor, the

distributor/manufacturer, the repacker, and the specialty manufacturer. (see Appendix)

Table 2

Types of Generic Companies	Specific Company Examples
Distributor	Rugby
Manufacturer	Mylan
Manufacturer/Distributor	Schein
Repacker	Rugby, Unit Dose Labs
Specialty Manufacturer/Marketer	Copley

The majority of generic companies are independent organizations, devoted solely to the manufacturing and/or distribution of generic pharmaceuticals. However, there are several major players that are generic subsidiaries of established PMA pharmaceutical companies.

Rugby-Darby, the market leader, concentrates on the distribution end of the business and supplies close to 300 products to the market. Goldline, like Rugby, is another major generic distributor supplying over 250 products to the market. These two firms, which are currently extremely successful in the generic business have a major weakness in that they do not manufacture their own products. They use large telemarketing forces and key account representatives that make orders and create shelf presence. However, both of these firms are left at the mercy of their suppliers for their products. Market research has shown that generic buyers are becoming increasingly concerned with firms that do not manufacture their own products. Reliable supply and consistency of product are crucial elements in this market, especially with chain drug store buyers. While firms like Rugby and Goldline are leading in the market right now, it is these weaknesses that are opening the doors for other kinds of generic drug firms.

Rugby is also considered to be a "repacker" company, which implies it takes other companies products, repackages them and sells them under the Rugby label. The reason one company can be a repacker and another can be a manufacturer is its own economic efficiencies. For some, it is simply more efficient and economical to distribute rather than manufacture products.

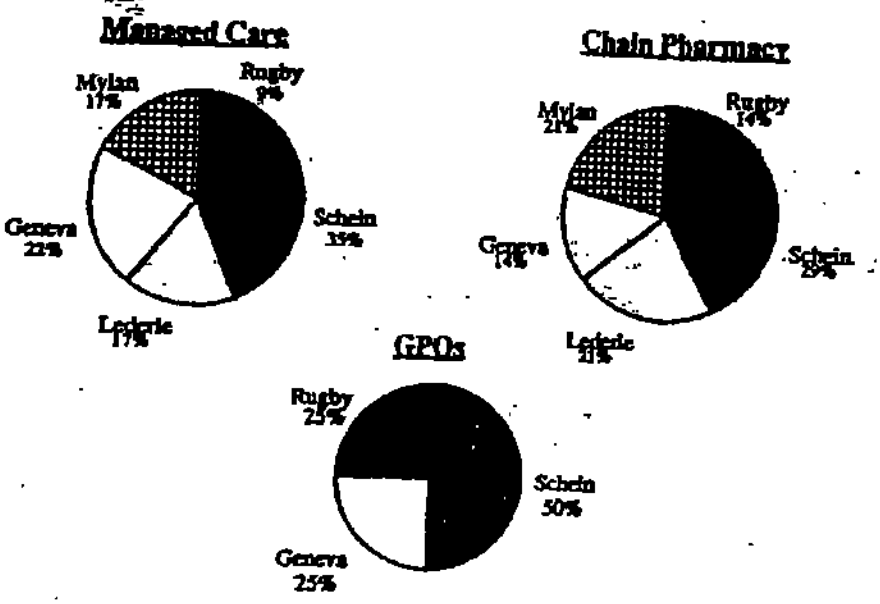
The generic drug firms which will most likely be dominant in the future will be those that manufacture their own products. Schein Pharmaceutical, which is already among the top five generic drug firms, has been making great

strides since their inception in 1985, and it is anticipated that they will become the market leader in the near future. Schein offers a large line of products, the majority of which they manufacture themselves. Market research has consistently shown Schein to be the most highly regarded generic drug firm among buyers in the industry today, precisely because of its manufacturing capabilities.

Another example of a firm that has gained great reputation through the quality of their products is Mylan. Mylan concentrates on producing high quality items. In contrast to Schein, which is both a complete manufacturer and distributor of their products, Mylan emphasizes only the manufacturing end and not the distribution end of the business. Mylan is also making increased attempts to become a "complete" pharmaceutical firm and not just a generic manufacturer. Mylan has recently acquired Dow B. Hickam, a supplier of wound care products, bringing a substantial hospital sales force (70 people) to augment Mylan's presence as a growing distributor. Mylan has made efforts to develop proprietary products such as Maxzide (their antihypertensive medication similar to Dyazide), and Eldepryl (a late stage Parkinson's disease treatment, that was acquired from Somerset Pharmaceuticals in a joint venture with Bolar). Mylan makes a concerted effort to manufacture specially selected items. While they don't have the product line of a Rugby or even a Schein (approximately 55 products), Mylan has witnessed some of the best returns in the industry with net income margins exceeding 30%.

In surveys conducted with managed care buyers, chain pharmacy buyers and hospital GPOs, Schein was the company that was consistently one of the favorites within the marketplace (Figure 9). Thirty-five percent of managed care buyers use Schein as their main supplier, as do 29% of the chain pharmacies surveyed and 50% of GPOs. Mylan was also ranked highly by the buyers and used as a primary supplier by 17% of the managed care buyers and 21% of the chain pharmacy buyers. As mentioned above, many of the key decision makers in this marketplace are becoming disenchanted with Rugby. While they value the broad product line that Rugby supplies, 40% of the managed care buyers have recently dropped Rugby as a supplier, and 67% of the chain pharmacy buyers reported that they have problems with consistency and pricing from Rugby.

Figure 9
Marketplace Trends in Generic Suppliers

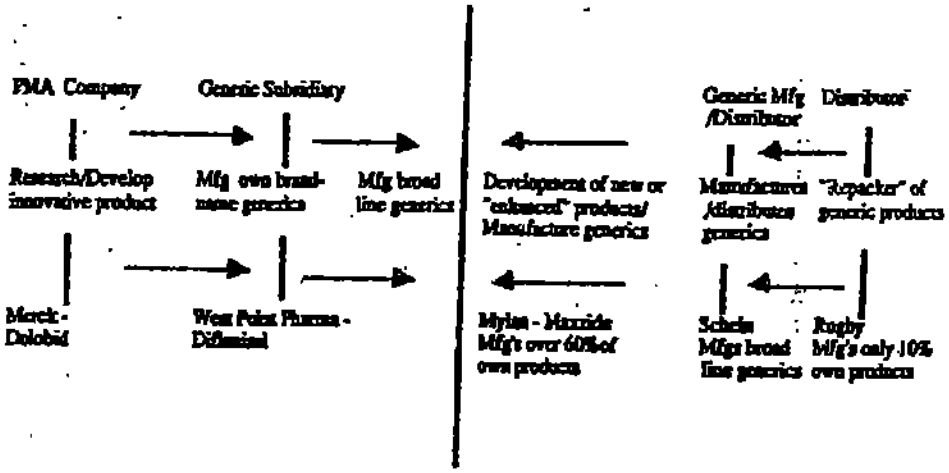


Other major players in the industry are generic subsidiaries of established PMA pharmaceutical companies. The most well known are Geneva Pharmaceuticals, a subsidiary of Ciba-Geigy, Warner-Chilcott, a subsidiary of Warner-Lambert, and Lederle Standard Products, a subsidiary of American Cyanamid. Originally, these subsidiaries were established or acquired as separate units to participate actively in the generic drug business (i.e. distribute generic versions of other firms' off-patent products) and not as a defensive strategy for their own products. It is only recently that these firms have started to make arrangements for distributing generic versions of their own off-patent products. Recently, Merck Sharp & Dohme has introduced a subsidiary, West Point Pharma, as an avenue to distribute generic versions of its own products. On April 13, 1993, Merck announced an expansion of West Point Pharma's generic product line by ten products, all of which will be sold by HMS.

Geneva and Lederle are two subsidiaries that were frequently mentioned in the market research. These firms (which manufacture the majority of their products) are valued for their high quality and consistent products. Twenty-two percent of managed care buyers use Geneva as their primary supplier for

research/development PMA companies and generic distributors are beginning to disappear. As the market has come to value consistency of product and reliability of supply, the pure distributors like Rugby, have been losing ground. In contrast, there has been a growing preference for the new manufacturer/distributors like Schein. In addition, the numerous patent expirations PMA companies are facing in the next several years seem to be forcing many to acknowledge their need for participation in the growing generic segment. As a result, some generic companies are emphasizing development of proprietary products and quality manufacturing, while PMA companies are beginning to establish generic subsidiaries in an effort to retain inevitable loss of market share. Figure 11 shows examples of the spectrum convergence.

Figure 11
Industry Spectrum Convergence



C. Buyer Decision Making Process

Market research indicates that competition is overwhelmingly based on price. However, companies are quickly realizing that it is not only the lowest priced product that gets the business. Generic buyers value and emphasize the need for a broad product line, value-added service and quality products. Service implies fast reaction to developments in the marketplace, good communication and the ability to remain price competitive. The

generic industry is a commodity market, one in which price attracts the customer, service and quality keeps them for the long run.

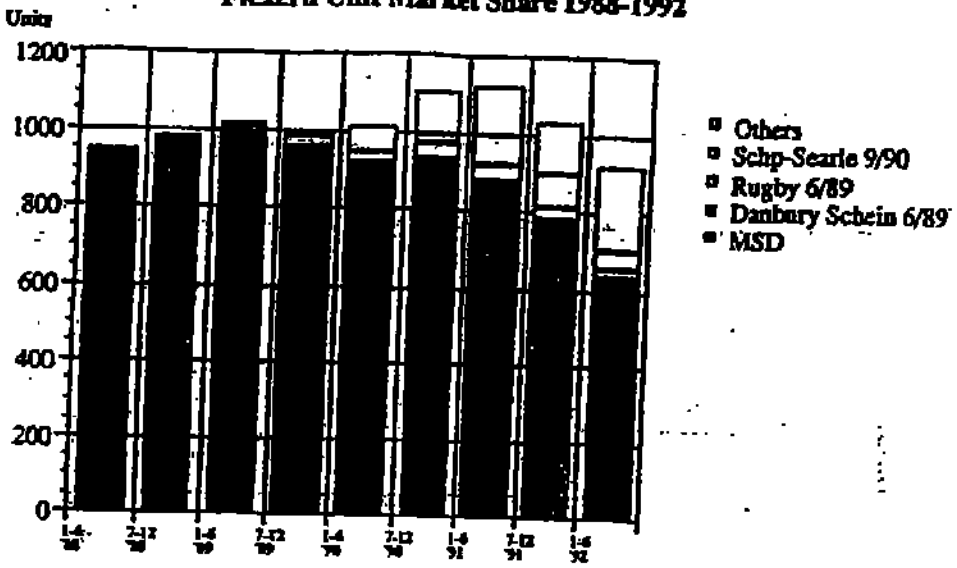
Of the over 400 generic products marketed, the top 30 as measured by number of prescriptions, account for 75% of the total generic prescriptions filled. Having a solid product line in these high volume products is clearly important to generic buyers if a company is to become a primary supplier.

Many of these top 30 generic products are very standard items. Nearly half of the items are some kind of antibiotic, anti-infective or analgesic such as Penicillin VK, and Acetaminophen with Codeine. The significance of having these products in one's portfolio is evident by examining the products carried by the major generic drug firms. Schein carries all 30 of these drugs, Rugby carries all but two, and Mylan carries over half (which represents a significant 31% part of their total products). Table 3 is a reference of a few of the top generic companies and the top 30 prescribed generics they carry in their product line.

Companies which manufacture their own products are beginning to develop a "preferred" status among generic buyers due to the importance of issues such as supply reliability and product consistency. It is also assumed by the buyers that a manufacturer will be in the best position to be a low cost supplier. A distributor has 20-25% operating costs, but a manufacturer only has 15%. It follows then that firms like Rugby (which repack and distribute 90% of their products) are beginning to lose favor with buyers as a result.

Also, critical to remaining competitive and being profitable in the marketplace is acquiring "first mover advantage". A 60 to 90 day lead over the second generic entrant combined with competitive pricing and solid service allows a competitor to gain and hold significant share in a given generic category. Once a drug hits the market generically, price begins a relentless downward spiral. This price decline occurs as more players enter the market and fight for market share. First entrant historically captures the largest market share. A good example of a company gaining significant market share by first mover advantage is Schein, with the generic Flexeril. (See Figure 12) Schein clearly has held on to market share as a result of being the first to market with the generic version of Flexeril. Not only is first mover important but the failure to respond quickly to pricing moves has caused some PMA companies to stumble in their initial ventures in the generic marketplace. Responses to competitive moves must be made within 24-48 hours.

Figure 12
Flexeril Unit Market Share 1988-1992



D. Industry Dynamics

The general nature of the generic drug segment directly contrasts the nature of the research based pharmaceutical companies. While PMA companies are used to making a great deal of investment with R&D, sales, and marketing, it is expected that there will be substantial return on that investment with sales and profit increasing every year for several years. When a generic drug is introduced the greatest profits are made on the first day in the first hour. The nature of the market forces prices and profits down that are never again recovered. The first entrant will generally price the product at 70% of the brand-name price. Price declines rapidly as each subsequent firm enters the market. The rate of reduction in price directly correlates to the number of entrants. With increasing entrants and price reductions, market share is lost and is usually never retrieved.

It should be noted that entry into the generic market by the innovator, with a generic version of its own brand-name drug does not hasten the brand's erosion. Two recent examples to demonstrate this are Tenormin and Feldene (see figures 15 and 16). Tenormin was introduced in the generic market prior to patent expiration, and saw branded share erosion (approximately 50-55%

within a year and a half) that is quite comparable to most other products. Feldene, on the other hand, had no innovator generic at all and lost close to 50% unit share within 6 months. Since generic diflunisal from West Point Pharma is the exact same product as Dolobid, one would expect that there would be 100% substitution, yet there is not. Even for Dolobid, the brand erosion is no steeper than is seen in the multi-source marketplace.

There are several factors that contribute to either promote or inhibit generic penetration. For any given product, the generic penetration will depend on the market size, the price, the therapeutic range, patient views and the number of competitors. Please see Table 4 for a list of the factors involved in generic penetration.

Table 4
Factors that Promote or Hinder Generic Penetration

Promote	Hinder
Size of market (large)	Narrow therapeutic window
Number of competitors (many)	Patient resistance
Price differential (brand vs. generic)	Low price differential
Patient acceptance	Acute care medication
	Difficult to manufacture

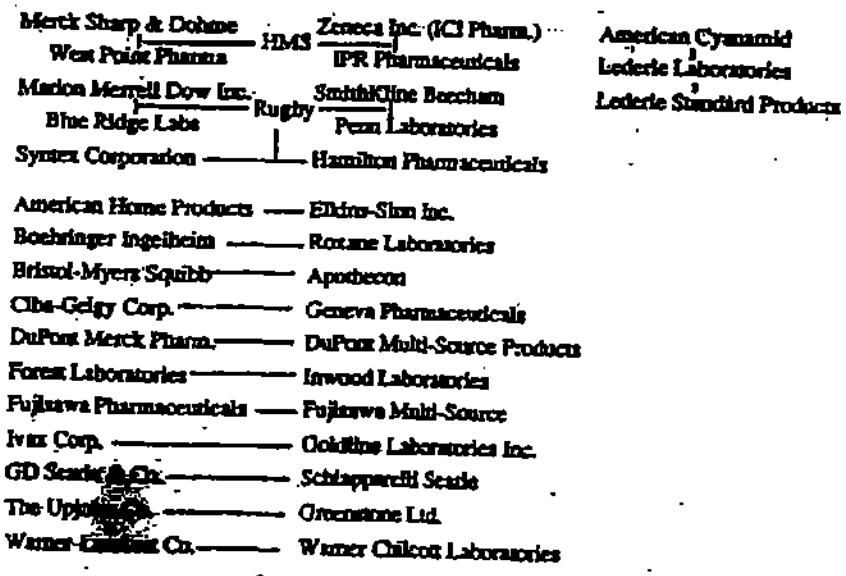
While the rapid reduction of price, profits and market share is one major difference between the brand segment and the generic segment of the industry, it certainly is not the only one. Vicious price wars are commonplace, and pricing decisions must be made within 24-48 hours. If a firm cannot move quickly in this market, it will not be able to succeed in it for the long term.

Because the highest profits in generics are made only in the short run, the ability to be first to market with any given product is crucial. The first entrant has the benefit of capturing the entire generic market and can enjoy profits until other firms introduce their versions. Subsequent entrants may not be able to steal market share from the first entrant quickly or easily, but they will be able to drive the price of products down. Depending on the number of entrants, and type of product, it is possible for the prices to be bid down to near cost within one year of generic entry. It is evident that in order to remain competitive and lucrative, generic companies must continually submit new ANDA's to the FDA and have new products to introduce to market regularly.

Chapter III
PMA Involvement in the Generic Drug Segment

PMA companies have long been associated with the generic drug segment of the pharmaceutical marketplace. They have become involved through strategic alliances, dedicated subsidiaries, and specialty divisions. Some firms have even begun providing products to the generic drug firms. Syntex has announced that it will supply the bulk ingredients for Naprosyn for any generic drug firm. Figure 13 shows the involvement of PMA companies within the generic arena.

Figure 13
PMA Generic Subsidiaries and Alliances



A. Strategic Alliances

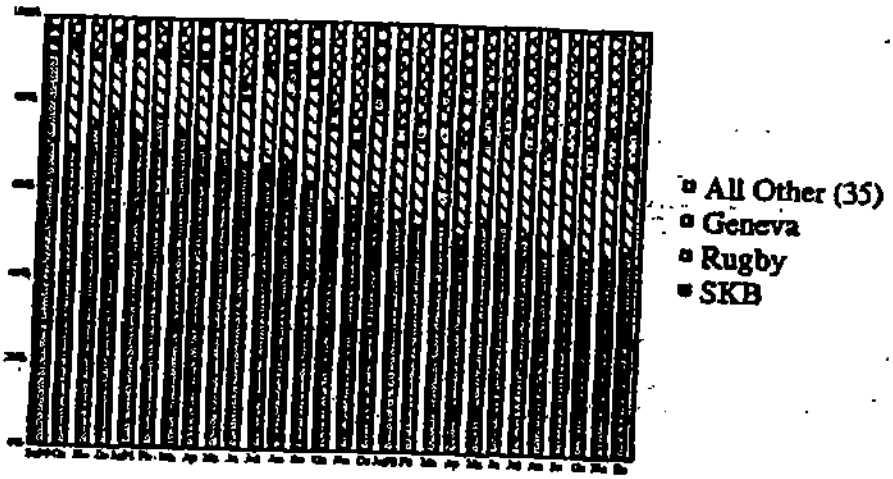
History

The first and most publicly celebrated alliance between a PMA company and a generic drug firm was made between SmithKline Beecham and Rugby-Darby in October of 1990. SmithKline Beecham gave the generic drug firm exclusive marketing rights to its anti-hypertensive agent Dyazide in exchange for an estimated 70% of revenues. This was done in anticipation of a new influx of generic versions becoming available at the conclusion of the generic scandal. Subsequent alliances have included Marion Merrell Dow and Rugby with MMD's calcium channel blocker Cardizem, and Upjohn and Geneva, with Upjohn's anxiety medications Halcion and Xanax. It has recently been announced that Upjohn will also be supplying Geneva with their nonsteroidal anti-inflammatory (NSAID) drug Ansaid, their diabetes drug Micronase, and their acne treatment Cleocin for generic distribution.

When alliances are made, the PMA companies normally establish a separate subsidiary that manufactures the product for the generic firms. SmithKline Beecham established Penn Laboratories, Marion Merrell Dow created Blue Ridge Laboratories, and Upjohn established Greenstone Ltd.

The data indicates that a strategic alliance is an effective way to retain sales and market share for a branded product going off patent that would otherwise have been lost to generic competition. While sales of Dyazide did go down, SmithKline Beecham, with their generic partner Rugby, were able to maintain close to 70% unit share of the Dyazide product two years after patent expiration. Since 50% of that unit share belongs to the branded product, it can be estimated that with SKB retaining 70% of Rugby's 20% of the market, (with the generic price dwindling to approximately 50% of the brand), sales retention would near 60%. Thus with generic participation, SKB was able to capture 70% unit share retention, and close to 60% revenue retention, while without generic penetration SKB would have been left with only 50% of the unit and dollar market. Figure 14 shows the monthly history of this endeavor from its outset in October of 1990 through December 1992.

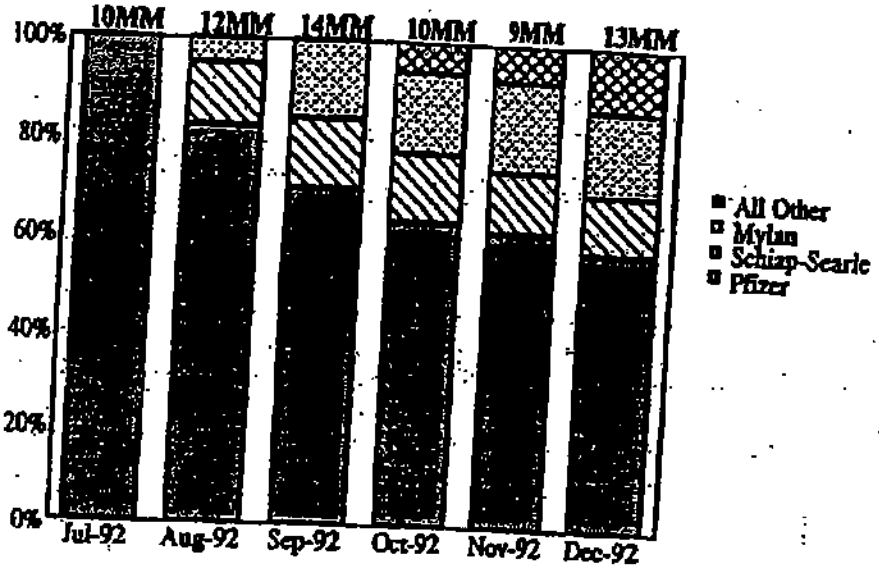
Figure 14
Dyazide Unit Market Share
September 1990-December 1992



Source: IMS

Failure to make some arrangement such as a strategic alliance will leave the company's products completely vulnerable to generic competition, and it can be expected that 50% of the unit share will be lost to generics within one year. All available data indicate that this erosion will occur with or without the participation of the innovator company. This point can best be demonstrated by examining what happened to Pfizer's anti-arthritic product Feldene (See Figure 15). The patent for Feldene expired in April of 1992. Pfizer made no effort to participate in the generic market for their product and by the end of the year had lost 45% unit share to generic competition.

Figure 15
Feldene Retail Unit Market Share
July 1992-December 1992



Source: IMS

While a strategic alliance can be an effective weapon to retain sales and share for a given product, if the purpose of an overall strategy is to form a presence and become a player in the generic drug marketplace then this option may not be the best to pursue. While the formation of an alliance would provide immediate access to the market, a broad product line to assist in gaining share, and sales support, it would offer no opportunity to learn about how the market operates or to create an identity within it.

If a strategic alliance were formed, the generic drug firm would request complete autonomy particularly for pricing. As mentioned earlier in this report, competitive reaction decisions in this marketplace are made within 24-48 hours. Any generic drug firm would require the freedom to make these quick decisions in order to stay on top of the market. With their own personnel and operations in place they would not need, nor would they generally want, any input from the innovator company. In addition, the generic firms are currently requiring 25-30% of the generic sales in exchange for handling the product.

It is important to also keep in mind that the biggest advantage for the generic firm in these relationships is the ability to be first to market with the product. Once they have achieved first entry, established themselves in the market, and have had the opportunity to develop the product on their own (or acquire it from a less expensive source), depending on the contract they might have the option of letting the innovator company go. This scenario would obviously leave the innovator company in a precarious position, suddenly losing their entire connection to the generic market.

B. Dedicated Subsidiaries/Divisions

Full-Line

Many brand name companies have long been significant players in the generic drug segment. They have participated by establishing or acquiring subsidiaries that are full-line generic manufacturers/distributors. One of the most well known is Ciba-Geigy's wholly owned generic subsidiary Geneva Pharmaceuticals. Geneva was acquired by Ciba-Geigy in 1979 and is currently one of the top 5 firms in the industry. Other well known PMA subsidiaries include American Cyanamid's Lederle Standard Products, and Warner-Lambert's Warner-Chilcott.

These firms were established with the intent to be full participants in the generic segment and thus take part in distributing generic versions of other firms' off-patent drugs. The subsidiaries are ideally supposed to act completely separately, and it is only recently that they have begun to distribute generic versions of the parent company's off-patent products.

Boutique

ICI

ICI pharmaceuticals (recently changed to Zeneca Pharmaceuticals) was the first PMA company which established its own division for the purpose of marketing its own off-patent drugs. In contrast to the generic subsidiaries discussed above, ICI established IPR pharmaceuticals in 1991 in an attempt to garner some of the inevitable generic share of its anti-hypertensive medication, Tenormin. IPR pharmaceuticals was essentially a "paper" company with two employees that utilized a contract sales and marketing agent, HMS Sales and Marketing, for their one product. HMS Sales and Marketing is a 15 person firm headed by Lawrence DuBow, former President of Lawrence Pharmaceuticals (a drug wholesaler sold to FoxMeyer

Corp. in 1990), and of the NWDA. Since that time IPR has released a second product, Tenoretic, again with the assistance of HMS.

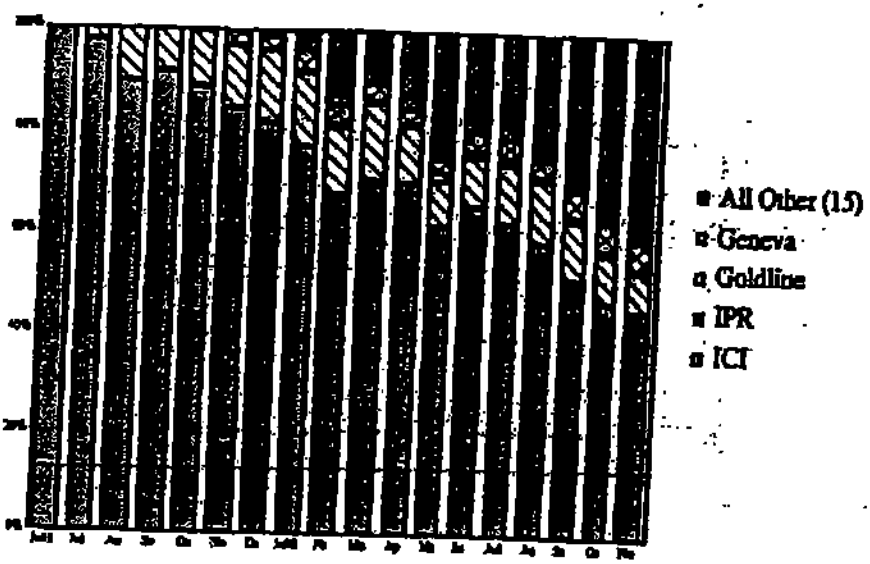
Interviews with IPR management indicated that HMS Sales and Marketing grew out of a relationship that ICI had with Lawrence DuBow. ICI had hired DuBow as a consultant in 1991 to help them flesh out the options that were available to them with regard to the inevitable generic penetration of Tenormin. DuBow recommended that ICI launch their own generic version of Tenormin (Atenolol) before patent expiration so as to fill the pipeline and establish themselves in the market. Because of the relationship that had been established between the company and DuBow, ICI felt comfortable using DuBow as the vehicle through which to accomplish this task. ICI had also considered going through Rugby, but because they would have more control with and pay less for the services of HMS, they decided to go with their own subsidiary.

Like any pioneer, ICI and HMS made mistakes and went through a learning process on this venture. The original marketing plan called for them to go exclusively through NWDA wholesalers. The original pricing was at a 17% discount to the brand (as opposed to the more traditional 25-30% price discount).

This team soon learned that having the product within the wholesaler does not create the "pull" or "shelf pressure" necessary to sell the product, and that creating relationships with generic wholesalers, chain pharmacies and other key classes of trade were vital for success in this business.

In addition to the initial pricing of only 17% off the brand, which was resented by the trade, ICI was also slow and reluctant in bringing the price down for their generic Tenormin product once other generic companies entered the market. This is evidenced by the clear and rapid deterioration in market share for ICI. (See Figure 16) Within a year and a half after patent expiration for their product, the combined unit market share for ICI and IPR was approximately 55%.

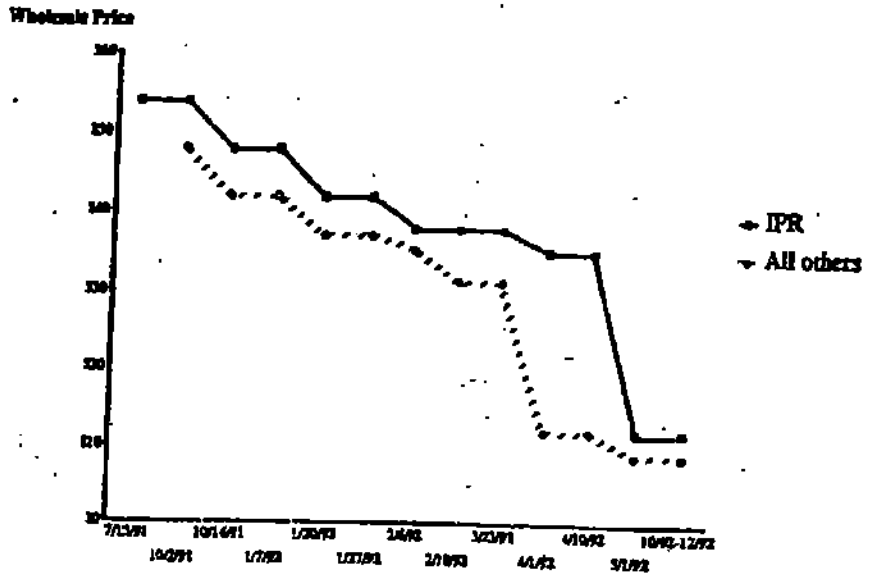
Figure 16
Tenormin Unit Market Share
June 1991-November 1992



Source: IMS

In addition to the dwindling market share, ICI witnessed dramatic decreases in the price of generic Tenormin. In the time period of July 1991 to the present, the actual wholesale price of Atenolol (in 50 mg/100s) dropped from $54 to $9. Figure 17 demonstrates this price deterioration over that period. It was ICI's inability to react quickly enough to the market, and reduce their price when others entered, that caused them to falter with their generic Tenormin product. This problem was precipitated further by the 17 other generic entrants.

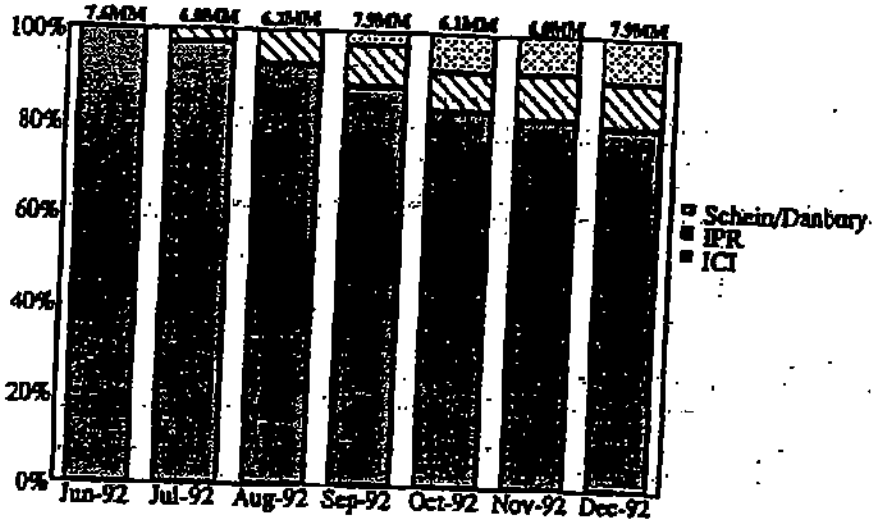
Figure 17
Generic Atenolol Actual Wholesale Price History
July 1991-Present



Source: HMS Sales and Marketing

ICI and HMS have attempted to utilize the insight gained with their first experience in the launching of IPR's second product Tenoretic. Tenoretic was introduced in July of 1992 at a 30% discount to the brand. Since that time only one other competitor, Schein Pharmaceutical, has come to market with their version. Schein came in at a price 10% below that of IPR, which IPR matched immediately. ICI and IPR currently retain approximately 90% of the Tenoretic market, however, the generic marketplace is split 50-50 between IPR and Schein. (See Figure 18) That Schein can enter as a second entrant and almost immediately gain equal share of the generic market for a product, represents the quality of their organization. With a broad product line (the majority of which they manufacture) and a strong sales force, they are a good example of the key elements necessary for success in this business.

Figure 18
Tenoretic Retail Unit Market Share
June 1992-December 1992



Source: IMS

Merck

At the end of 1992, Merck attracted a great deal of attention with their establishment of West Point Pharma, a new division which was created to market generic versions of their recently off-patent anti-arthritic product Dolobid (diflunisal). Like IPR Pharmaceuticals it is also a "paper company" with three employees that directs marketing efforts. Merck also employed the services of HMS Sales and Marketing as a contract sales organization.

Interviews with Merck staff and industry consultants indicate that Merck's venture into the generic marketplace with West Point Pharma was intended to be an experiment. It offered them an opportunity to "dip their toe" into the water without sacrificing or committing to anything. By utilizing HMS Sales and Marketing, Merck felt that they would be able to keep some distance from the generic marketplace until they had decided on whether or not to become fully involved. The decision to become fully involved appears to have become a lot clearer, as interviews with key management personnel at Merck have all but confirmed their desire to be a critical mass player in this market within the near future. This is also evidenced by some

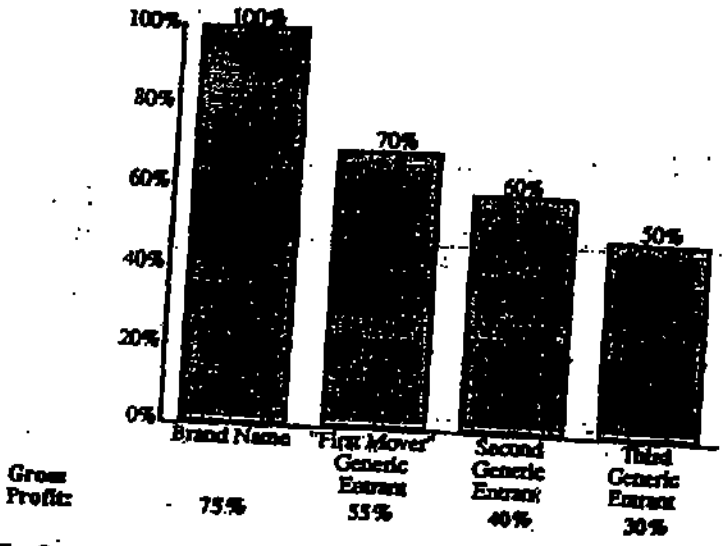
of the latest activity in the market as Merck has recently announced that West Point Pharma will be distributing ten generic versions of off-patent products in addition to their centerpiece Dolobid. These products are anticipated to be generic versions of Merck's own products that have been off patent for some time and include Aldomet, Indocin SR, and possibly Clinoril and Sinemet. HMS will be representing Merck as a sales agent for all ten of these products, in addition to generic Dolobid.

Chapter IV
Economics of the Generic Drug Segment

A. Financial Dynamic

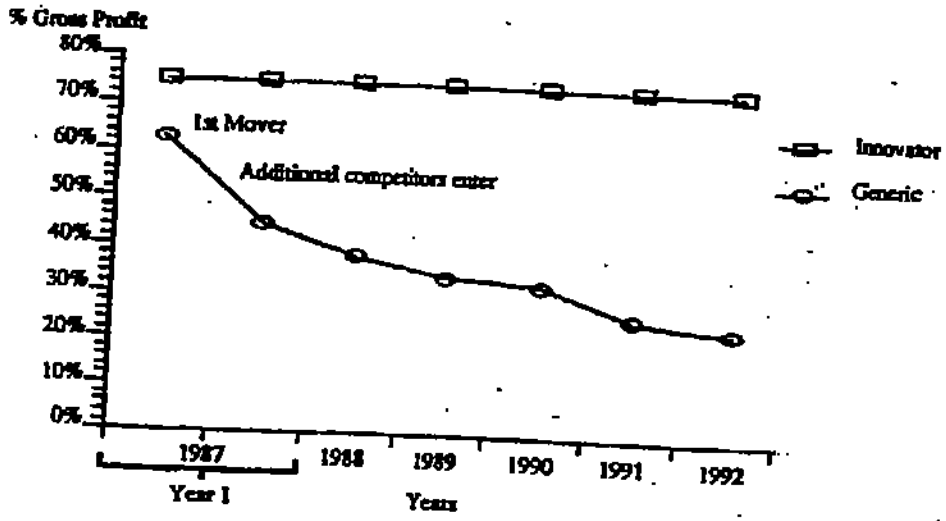
The economic structure of the generic drug segment is entirely different than that of the branded portion of the pharmaceutical industry. Depending upon the market opportunity of a branded drug going off-patent, numerous generic manufacturers will have ANDAs already approved (or soon to be approved) and waiting for the expiration of the patented product. Once the patent expires, those manufacturers will scramble to gain first mover advantage. In the generic sector, the first entrant will initially achieve attractive gross margins; however, those margins will erode significantly and rapidly as additional competitors enter the market. In the majority of cases, the first entrant will enjoy high margins for a short period, lasting for several weeks or at most, a few months. As indicated in Figure 19, the first entrant is usually priced around 20-30% below the brand-name drug and makes gross margins at approximately 55-60%. To obtain market share, the second entrant typically prices at a 30-40% discount, and the third entrant around a 50% discount. By the time the fourth generic enters the market, prices are one-half the level of the branded product and the gross margins may be 30% or less.

Figure 19
Typical Generic Drug Pricing and Profitability



To further demonstrate how pricing strategies affect gross profit margins, Figure 20 shows the pricing dynamics once a branded drug goes off-patent. The graph estimates gross profit margins for the innovator of Cephalexin, the first generic entrant, and other generic competitors that followed suit. The innovator of the drug suffered substantial volume decreases as generic competitors entered the market; however, unit price increases offset the volume decline leaving gross profit margins unchanged. As shown, when additional competitors entered the generic segment, gross profit margins eroded rapidly.

Figure 20
Innovator vs. Generic-Typical Gross Profit Trends

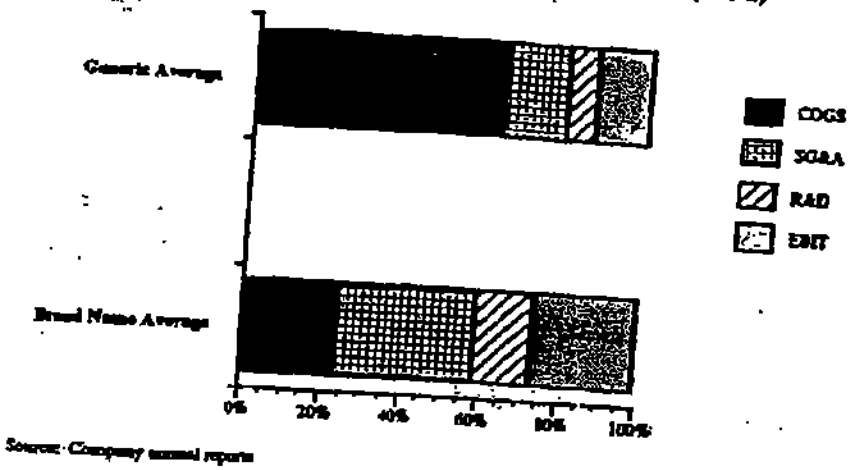


Source: IMS

As evidenced by the operating profile comparison (Figure 21), operating ratios of traditional pharmaceutical and generic firms differ substantially. In order to have equitable comparisons, our generic composite includes six firms that manufacture most of their product line rather than those that repackage or distribute. Included in the branded composite are six PMA companies whose pharmaceutical sales as a percent of total sales exceeds 70%. Cost of goods sold represents 63% of the generic composite while only 24% of the branded composite. Generics are a high volume, low margin business. A generic firm has to sell three to five times what the branded firm has to sell to earn an equivalent amount. Other costs are inherent in this business as well; with stiff competition in generics, companies are forced to work on shorter lead times which further increases production costs.

As expected, sales, general and administrative costs are a higher percentage of revenues for branded firms than their generic counterparts. The major difference is that branded firms actively "detail" their drugs while generic firms compete in a commodity business and can not afford to use the same strategy. Furthermore, few generic firms offer proprietary products; as a result, research and development costs are much lower for generic firms.

Figure 21
Operating Profile - Traditional vs. Generic (1991)



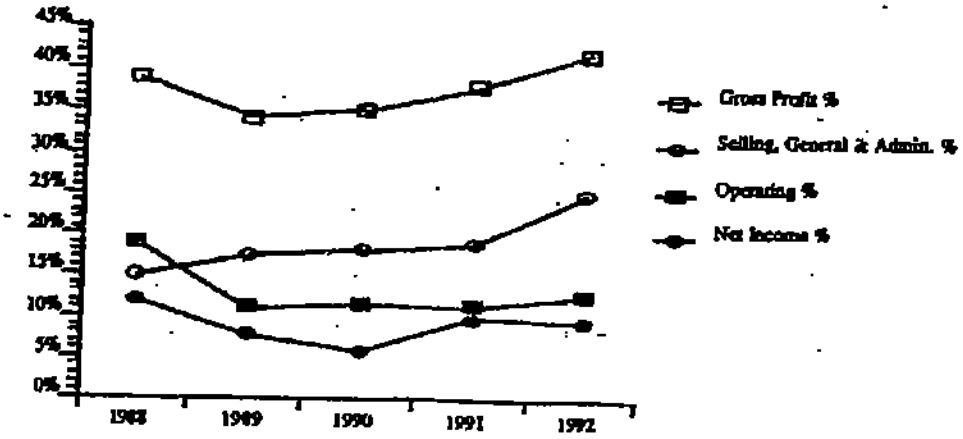
Source: Company annual reports

In contrast with the PMA companies, generic companies are in a low risk (low R&D), low return business. A research based pharmaceutical firm can afford to invest heavily in a new drug because of its patent protection. Significant costs are justified over the life of the patented product as the initial investment is recovered and profits are achieved. A typical generic firm has far less initial investment before a particular product is launched; initial returns are not only short lived but will rapidly decline. Due to low initial investment, generic firms capture initial costs quickly but sustain minimal returns over the life of the product. In short, generic companies face a short term profit window and are forced to continually search for new opportunities.

B. Current Financial Profile

As a result of the economic structure of the generic segment, generic drug participants run their operations "lean and mean". With the majority of their expenses in cost of goods sold, generic manufacturers operate their businesses with little overhead. As the composite indicates (Figure 22), net income over the last four years has ranged from 6% to 10%. However, companies with focused strategies such as Mylan and Copley have demonstrated higher profit margins. As mentioned, price erosion is very much a function of the number of competitors entering the market and dictates profitability for the generic segment.

Figure 22
Generic Drug Industry Composite - (1988-1992)



There are also companies who have emerged over the past five years with strategies that combined low cost manufacturing with "cherry picking" generic drugs that have either low market value, and thus fewer competitors, or drugs which are more difficult to formulate; thus, requiring a higher level of technical skill than is usually resident in generic companies. In addition, some of these companies are seeking to develop their own proprietary products by applying sustained release and other "modified" technologies to generic drugs. These companies, Copley, Mylan, and Schein as examples, have managed to achieve quite respectable net margins ranging anywhere from 20 to 33%.

Several emerging forces may dictate future margins for the pharmaceutical industry. Cost containment objectives from the government, managed health care organizations and third party payors have been and are expected to increase.

Cost containment pressures from the government, managed health care organizations, and third party payors will be dictating the use of lower priced pharmaceuticals. One trend is an increasing percentage of the nation moving to managed health care. As a result generic substitution has been increasing rapidly. In 1985, approximately 20% of all new prescriptions in the United States were filled as generic. In 1991, this figure grew to 34%, which represents an annual growth of approximately 10% per year. By the year

2000, it is anticipated that 50% of all new prescriptions in the United States will be filled as generic. As a result of increasing penetration in the low margin segment, overall profit margins in the pharmaceutical industry will decline.

In general, generic drug firms either position themselves as manufacturers or repackagers. Through our market research and industry analysis, it is apparent that manufacturers are clearly in a better position to achieve higher profit margins than those that repackage. Market research indicates that manufacturers are preferred over repackagers in issues such as supply reliability, product consistency, and the ability to control costs. In this segment of the pharmaceutical industry, profit is a function of how low manufacturing costs are. A repackager has no direct control over the cost of the drug and, in fact, relies on competitors to supply them with product.

C. "Specialized" Generic Drug Firms

As mentioned above, a few generic drug firms have successfully maintained impressive profit margins by concentrating on products which are: proprietary, require greater manufacturing expertise, have smaller market opportunity ($35 to $75MM), or offer sustained or modified release technology. Mylan and Copley have employed a combination of these strategies.

Mylan's success has been a combined strategy of a proprietary and generic focus. Mylan has two proprietary drugs that it developed on its own, and as part owner of Eldepryl (Somerset Pharmaceuticals - anti-Parkinson's disease). In addition, the company has extended its proprietary arsenal by recently acquiring a branded manufacturer of wound care products.

Currently, Mylan's generic product line consists of 55 generic products in varying strengths covering 19 therapeutic classes. The company manufactures generics with narrow therapeutic windows such as anti-angina drugs and beta blockers. As such, Mylan has few competitors in those categories. In addition to unique capabilities, a large portion of their product line is dedicated to tablet and capsule forms. These variations are the easiest to duplicate; hence, competition is fierce. However, due to its long-standing consistency and stringent quality standards, the company has earned a top spot as one of the leaders in these dosage forms.

Mylan takes advantage of favorable tax rates in Puerto Rico and technical efficiencies on the operational side to boost its bottom line. As a result, the

company achieved net profit margins of 32.6% in 1992. Currently, the stock is trading in the mid-twenties with a price earnings ratio of 30.

Another example of a specialized strategy, Copley blends its technical expertise with non-blockbuster generic drugs. By selecting products with smaller market opportunity, Copley has fewer than four or five competitors in most cases; there is no competition whatsoever in eight of its products. Copley typically targets drugs in the $5 to $75 million category, the kind of generics that most companies do not seek. Also, by combining technical expertise to formulate new dosage forms for these products, it creates its own unique markets. The company has anticipated well the products that have switched to OTC status, thereby extending the product life cycle.

Copley markets 24 products covering eight therapeutic categories. The company has one of the broader product lines from the standpoint of the various dosages that it can manufacture. Those forms range from extended-release tablets, capsules, powders, and effervescents, to various types of solutions, suspensions, syrups, and ointments and creams. More unique is its ability to produce foams, aerosols and buccal patches (transmucosal patches for the mouth). Some examples of Copley's product line include generic versions of Ciba-Geigy's Slow K, Warner-Lambert's Procan SR, and J&J's Haldol.

This combination of products and technological expertise have given Copley some of the highest margins in the industry; 1992 profit margins were 25.3%. Currently, the stock is trading in the high 30s with a price earnings ratio of 45.

Copley and Mylan have good formulas for success in the generic drug segment and have benefited from those strategies. Thus, it is possible for a company to exploit specific opportunities within this marketplace. A manufacturer with capabilities in forms which require greater technical skill can carve out a specific niche within the generic market. As a result, a company could position itself as a potentially low cost manufacturer and often, compete in a market with relatively high barriers to entry thus, fewer competitors.

Chapter V
Schering-Plough Strategic Options

Having accepted that our objectives are to:

1. Protect and extend the life cycle of our branded products.
2. Create leverage for our branded products in the Managed Care environment.
3. Establish an effective defensive position for Schering multi-source products.

It is necessary to explore the strategic options which would enable us to achieve these objectives.

The analysis has shown four basic options for participating in this marketplace.

Option A. Strategic Alliance with an Existing Generic Drug Firm

By forming an alliance with an established generic player it will enable us to retain sales and share for our soon to be off-patent products that we would have otherwise lost. This strategy is clearly a short term option and would not position us as well in the long term.

There already exist a number of examples of PMA companies utilizing generic companies as outlets for generic versions of their proprietary drugs coming off patent: SmithKline Beecham with Rugby, Marion Merrell Dow with Rugby and Upjohn with Geneva. The advantages of this approach are that it provides immediate access to the generic markets through a well established player, inclusion in a "critical mass" product portfolio that increases the likelihood of market penetration, and elimination of the need for financial and management resources to be devoted to this issue.

The disadvantages are financial and strategic. Most of these alliances are based on the generic company retaining 25-30% of the net sales volume in exchange for their marketing and distributing the product. For example in the case of Proventil Inhaler, if we assume a combined Ventolin/Proventil Inhaler market of 500 million dollars, generic penetration of 50% in the first year, the generic selling at 70% of the branded, and a Schering produced

generic capturing and retaining 35% of the generic market in the first year through first mover advantage, the revenue produced by the Schering generic would total 61 million dollars. Of that amount, at least 15.3 million dollars would be retained by the generic "partner" in exchange for their services. This is a seemingly very high price to pay.

From a strategic perspective, the use of an alliance would not allow us to achieve our objective of establishing a strategic position from which to defend ourselves in the generic marketplace. We would gain no first hand knowledge of the market and the competitive dynamics. While such an arrangement would allow us to meet the short term need of handling generic competition for Provenil Inhaler, it would do nothing to achieve our longer term strategic objectives of defending our multi-source brands and leveraging our managed care business.

We therefore conclude that a strategic alliance with an established generic company is not a recommended option.

Option B. Utilize a Contract Marketing and Sales Agent

One way to meet our objectives in this market is to do so gradually with the assistance of a contract marketing/sales agent that has experience in this market. By doing so we would be emulating the strategy that Merck employed. Merck's establishment of West Point Pharma, was intended to be an experiment which would determine Merck's ultimate decision of whether or not to be a complete player in the market. In order to keep their generic operation at an arm's length they utilized the services of HMS Sales and Marketing, Inc. to distribute generic versions of its arthritis drug Dolobid. By using HMS, and marketing one generic, Merck has benefited by gradually establishing the operation within the generic market and learning the dynamics of the business from HMS and their own involvement. As such, Merck has allowed itself great flexibility regarding its decision of whether or not to fully commit to the generic market. Merck's intentions have become clearer through its announcement that it will add 10 more off-patent drugs to its generic arsenal.

Since we lack the practical experience in this market the use of an HMS organization would allow us to gradually learn about the market while our products benefit from an established distribution channel. Their experience and knowledge of the industry would certainly be beneficial as we try to understand a market that is foreign to us right now. While we would also be forced to sacrifice sales under this option, the cost would be cheaper, 8-12% of sales, than if we chose to pursue a strategic alliance.

One of the major disadvantages to an HMS organization is that, as mentioned earlier in the report, generic buyers, especially chain buyers, want to deal directly with the manufacturer and view HMS merely as a middle man. Distributing our products through HMS may very well send the wrong message to the market and disrupt our long term objectives. (see Appendix 4 for background information on HMS)

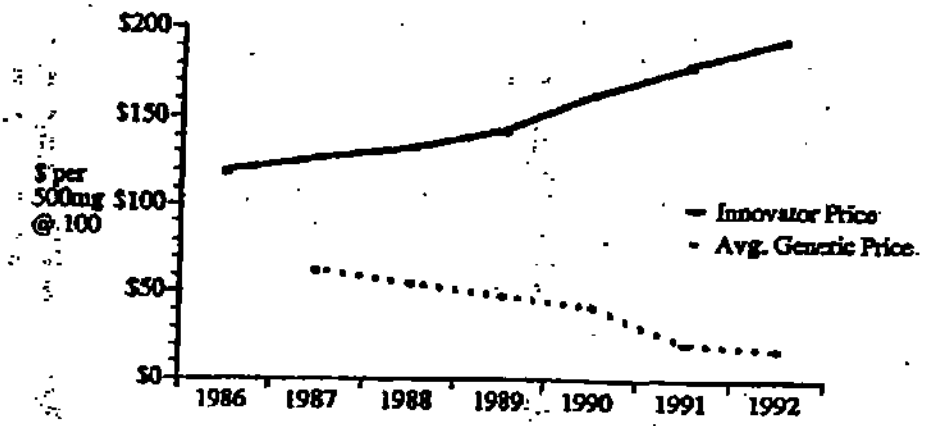
Option C. Acquire An Existing Generic Company

The most expeditious way to enter and become a force in this marketplace quickly is to acquire an established company with an existing portfolio of ANDAs. This would provide an established entry vehicle for generic versions of our products. It would also provide us with the "critical mass" of generic products which market research indicates is necessary to be considered a primary supplier for most drug store chains, wholesalers and large managed care accounts. Further, it would bring an established capability to produce the volume of new ANDAs necessary to stay competitive in this marketplace.

In viewing the acquisition of a generic drug company it must be recognized that the existing stable of ANDAs which the company comes with represent a deteriorating asset. The peculiar economics of the generic marketplace dictate increasingly rapid penetration of generics once a drug is off patent. However, price erosion for generic products can occur just as rapidly depending on the size of the market and the number of competitive entrants. As a consequence, the generic company which has the first mover advantage for a drug just coming off-patent can expect to see its unit volume peak in the first or second year and price deteriorate steadily with the entrance of each new generic competitor. (See Figure 23)

Figure 23
Cephalexin (Keflex) Generic Penetration

Generic Competitors	1	28	28	32	30	28	31
Generic Penetration	0%	40%	70%	78%	82%	88%	90%

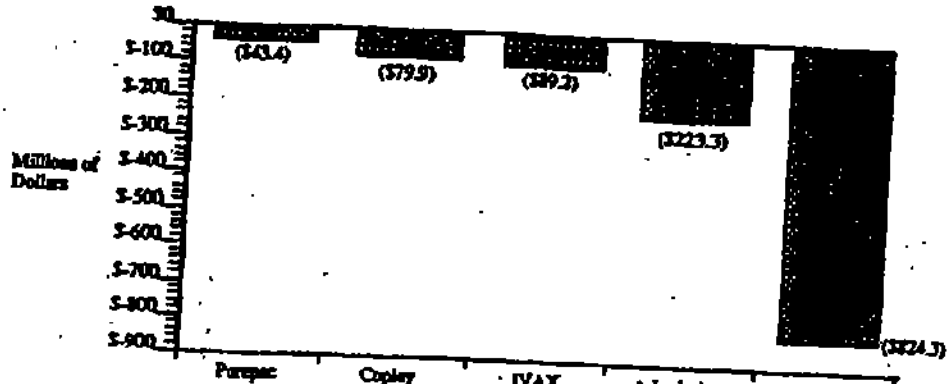


Source: IMS

This dynamic applied to an acquisition analysis means that the value of existing ANDA's will almost inevitably erode year by year. This is a segment of the pharmaceutical industry in which price increases are virtually non-existent and prices cannot be sustained for a period of time. The real underlying value of a company under consideration for acquisition therefore is not the current revenue stream, but rather the volume and quality of the ANDA portfolio it has filed, and its existing position with large buyers as a "preferred supplier."

Unfortunately, market factors have boosted the valuations of most publicly traded generic companies beyond any reasonable acquisition level. (See Figure 24) A profile of major generic drug firms is included in Appendix 4.

Figure 24
Generic Firm Acquisition - NPV Analysis (1994E - 2000E)



	Purepac	Copley	IVAX	A.L. Labs	Mylan
IRR:	1.54%	2.9%	10.5%	(74.9%)	(19.3%)
1992 Sales (MM's):	$64.5	$39.8E	$460E	$301.3E	$151
Gross Margin:	50.4%	56.8%	42.0%	44.0%	57.0%
Operating Margin:	25.0%	30.6%	13.0%	14.0%	32.5%
Net Income Margin:	23.2%	25.3%	9.7%	5.8%	32.6%

Note: NPV calculations assumes a discount rate of 14% and an acquisition cost of 51% common stock. Model is driven by 51% of projected cash flows.

Source: Company annual reports

Immediate access to entry into this marketplace to attain previously-mentioned strategic objectives can be achieved with the purchase of an existing generic organization. However, given the current premiums that would be commanded by these firms, it would not be financially justified at this time. Should market conditions change, we will re-evaluate the viability of aquiring an existing company.

D. Expansion of Warrick Pharmaceuticals

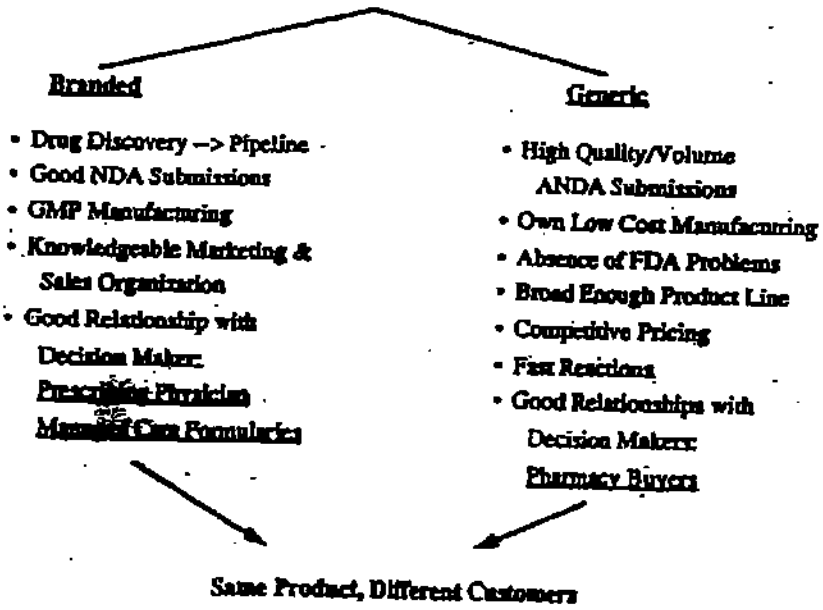
The final and recommended option is for us to create our own small, internally developed organization. While the entity, Warrick Pharmaceuticals would be developed internally, the intent is for the organization to function with the instincts, economic structure and competitive profile similar to a generic company. Again, the objectives in creating the entity are to extend the product life cycles of our off patent products build a generic product portfolio which offer sufficient value so as to create interest and leverage for our branded products in the managed care

segment. In addition, we will be able to effectively defend our multi-source products in an evolving marketplace while learning the dynamics first hand.

Expanding our own subsidiary will allow us to directly pursue our primary objectives. Exercising this option does, however, raise a series of issues which must be addressed if the strategy is to be successfully executed.

The one issue which all participants and observers in this segment of our industry agree upon is that a research based company seeking to compete in this marketplace must keep their generic and branded marketing operations separate. As the earlier analysis demonstrated, nearly every aspect of the generic business differs significantly from the branded business. As the following table indicates, the characteristics which define successful companies in these two segments are radically different. (Refer to Figure 25).

Figure 25
Key Success Factors



When we look at the possibility of developing our own generic company three primary issues come to the forefront:

- Product Supply
- Organization
- Entry into the Market

To present value to our managed-care customers we must be able to achieve distribution of our generic products in the retail distribution channels, particularly the chain drug stores.

Market surveys, as well as qualitative market research, have clearly indicated that for a generic company to be considered as a primary supplier to the chains, it is necessary for the company to present a "critical or strategic mass" of products. This critical mass can be defined as 10-20 products which are valuable to the market. We will be able to introduce generic versions of our own major products (e.g. Proventil) once we know that generic competition is inevitable. In addition there are twelve other products of our own that we could fit into a generic line immediately. While that puts us into the range of the 10-20 product portfolio which we will need to be successful we must have a continuing pipeline of products to remain interesting to the market. While we can begin as a 12 product company, we will need to have a clear vision as to what other types of products we want to add to the portfolio and the time frame within which we can acquire the generic products to sell.

There are five potential sources of products:

1. Our own off-patent products
2. Generic products which we formulate, apply and receive ANDAs for
3. Off-patent products of other PMA companies which we market on their behalf
4. ANDA approved products we would gain through the acquisition of an existing generic company
5. ANDA approved products manufactured by another generic company which we would purchase and distribute.

Each of these sources of products have pros and cons, time, margin and strategic image dimensions to consider.

Our own off-patent products are the least problematic. They would provide us with the best overall margins and would promote our reputation in the generic market segment since we are the innovator/manufacturer. The

following is a list of selected products from our off patent portfolio, generic versions of which could be marketed by Warrick.

Proventil Syrup
Proventil Solution
Proventil Tabs
Valisone
Diprosone
Garamycin Cream
Metimyd
Permitil
Etrafon
Trilafon
Polaramine

These products have been off patent for periods ranging from 3 to 11 years. Generic erosion of unit market share ranges from 50 to 90 percent. The cumulative dollar volume in 1992 for the generic equivalents of these Schering products generated $115 million.

Generic products which we would formulate and then go through the ANDA process on our own, assuming we would be among the first into the market, would be the second most desirable, both from a economic and image perspective. By being the manufacturer we would garner decent margins and from the view of the marketplace we would be seen as a reliable and durable supplier. The drawback is time. The ANDA approval process can take from 18 months to two years once the application is filed. Prior to the filing process, development and bioequivalency testing must be completed. The time from initiation of development to having an approved ANDA can be up to three years. The total cost to develop the product and go through the ANDA process can range from 350,000 to 1 million dollars per drug.

Since we are going to be long term competitors in this market, we will need to participate in this process. We will become proficient at filing high quality ANDA's. The good news here is that the Office of Generic Drugs has committed to reducing the time to process ANDA's to one year by 1994. However it is clear that this process will yield products for our portfolio in 1995 at the earliest.

Getting off-patent products from other PMA companies to market on their behalf is another possibility. With the large number coming off patent within a few years, there is no shortage of PMA companies examining this issue as

we are today. Our discussions with Merck concerning West Point Pharma brought forth the point that they would like to examine marketing other PMA companies' generic products.

This route would provide the first mover advantage, but we would still be selling a product someone else made. We would be able to make decent margins given the 25-30% of sales other generic companies are charging for marketing PMA generics.

An acquisition of an appropriate generic company would provide us with a product portfolio and hopefully a good pipeline. By definition, we would be a manufacturer, and we would acquire management capability in this segment which we do not currently have. The real question here is price. As the earlier examination of the option indicated the purchase price for most generic firms is not economically justifiable.

The final option of buying products from other companies and distributing them at low/no profit margins brings with it the obvious issue of very low returns and being perceived by the marketplace as a "repacker". It would fill out a portfolio in the short term but would create no sustainable value.

Figure 26 summarizes these product supply options.

Figure 26
Summary Chart of Product Supply Options

Options

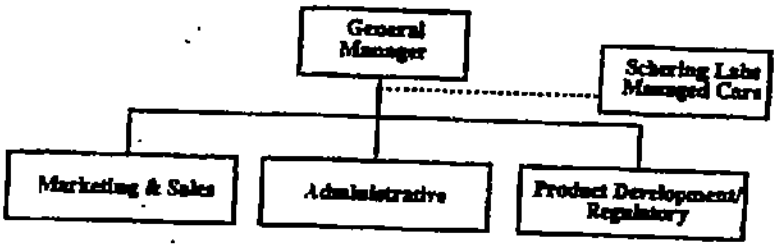
	1 - Our Products	2 - Subunit ANDAs	3 - Other PMA Products	4 - Acquire a company	5 - Purchase ANDAs
Time	• Immediate	• 1-2 years	• 3-6 months	• Immediate	• 6-12 months
Cost	• Nothing	• $350K-$1MM	• Sacrifice 70% of generic sales	• $150-200MM	• $1-2MM
Margin	• 30% of brand	• 10-20%	• 25-30% of PMA net income	• 10-20%	• 10-20%
Strategic Impact/ Achieving our Objectives	• Creates presence, but limited immediate line	• Long Time line	• Limited opportunity	• Full presence, full line	• Full line, but costly/ time consuming

The organizational issues are also critical in addressing how we would build our own generic company. We will need to recruit experienced personnel

from the generic industry to help us "get down the learning curve." The prospect of using HMS, Inc. as a contract vehicle to help our subsidiary launch Proventil and gain practical experience in working in this market has been raised as an alternative to a strategic alliance or purchasing a company. While HMS charges 8-10% of sales as opposed to 25-30% for Rugby et al, it is still a lot of money. Using the same example for Proventil Inhaler cited earlier, we would end up paying HMS between 5 and 6 million dollars for introducing the product. Recruiting talent from good generic companies appears to be a more cost effective route.

Based upon an examination of the organizational structure of companies like Mylan, Schein, Par and others, we believe that the following organization chart (Figure 27) presents a likely structure of our own generic subsidiary.

Figure 27
Suggested Organizational Chart: Warrick Pharmaceuticals



We expect that about half of the personnel required could be provided through existing resources without replacement. The start-up organization will be a skeleton with only about 5-8 persons and grow to no more than 15 persons only after demonstrated success in specific product and market targets. The administrative costs will be minimal in the first year, about $500,000 and grow to no more than $1 - 1.5 million when fully operational. This will be supplemented by some minimal shared services such as customer service, legal, financial, etc. where necessary. Only about one-half of these costs will be incremental. Additionally ANDA funding will be required on a product by product basis and is estimated to be about $5-8 million in total over the next 3-4 years. Manufacturing and distribution requirements will be provided through existing Schering facilities and costs willl be passed along on a direct basis.

Chapter VI
Generic Strategic Plan

The strategy necessary to achieve entry focuses on the following:

A. **Protect and extend branded product life cycles as patents expire.**
Utilize all available means, line extensions, regulatory challenges, market positioning and legal challenges to maximize the protected period of our products. Each product must be individually assessed to determine the mix of strategies which will accomplish this objective. This includes being first to market with generic versions of our own products.

B. **Seek to create leverage for our managed care buyers.**
Economic value will be offered to selected managed care buyers by providing them with generic products. By developing a sufficient portfolio to gain chain distribution, we will position ourselves to offer real value to managed care customers through presentation of an attractive product mix that includes branded and generic products.

Key Elements of the Strategy

A. Protect and defend branded product life cycles as patents expire.

Below is our Proventil Inhaler defense strategy. This strategy will provide us with a model for the defense of future products as they encounter potential generic competition. Recognizing that individual product situations vary, these tactics will be reassessed as appropriate.

1. Proventil Inhaler Defense Strategy

Proventil Inhaler product management has been very successful in employing strategies which have delayed the introduction of generics. Regulatory and legal challenges have had the effect of preventing guidelines for generic inhalers from being issued. While these strategies may continue to bear fruit, we are now at the point where the possibility of facing generic competition within nine months is quite real. We are now prepared with a contingency strategy for facing that eventuality.

Historically, we would let a product like Proventil go off patent, lose share and continue to raise price. This resulted in a rapid decline in unit volume and a somewhat less rapid decline in revenue due to increasing price on the share that we retained.

Today, we know that price increases significantly above inflation are not likely. We also know that by being the first to introduce a generic version of our own product, we can capture and hold a significant share of the generic portion of the market. To prepare for eventual generic competition we modeled three scenarios concerning Proventil Inhaler off patent.

Our general assumptions were:

- FDA will issue guidelines on generic MDI's by June 1, 1993
- If guidance has been issued by mid-1993, we expect generics to launch by January 1994
- 40% of units in the combined Proventil/Ventolin market will go to generic equivalents in the first year
- Price erosion, based on historical models, increases rapidly from 40% in year 1 to 60% in year 2, up to 70% by year 5.

The Scenarios explored were:

Scenario I: Neither Schering nor Glaxo enter with a generic product
Scenario II Schering and Glaxo both enter with generic products
Scenario III Schering, but not Glaxo introduces a Generic Inhaler 60-90 days before other generic competition

Based on those assumptions applied to an experience based model of share and price erosion for generic drugs, the following five year NPVs were derived for each of the scenarios:

Scenario I (Do not enter the generic market)	$345 Million
Scenario II (Schering & Glaxo enter)	$360 Million
Scenario III (Schering enters alone)	$380 Million

Each of these scenarios has pros and cons which can be articulated as follows:

Scenario I
Pros:

- No cost of infra-structure development
- If generic never hit/indefinitely delayed, keep branded profit

Cons:

- Loss of profits due to 40% generic erosion in the first year
- Window of opportunity lost to be "first mover" in the generic market
- Glaxo may move first. Loss may be greater.

Scenarios II & III
Pros

- Higher NPV
- Capture first mover advantage. Proven to be able to hold highest unit generic volume with this position
- Act as experience model for future products
- Potential vehicle for bundling or other private label opportunities
- Price flexibility in generic does not affect branded price
- Shift generic impact to Glaxo brand
- Integrate generic with Proventil brand at trade level

Cons:

- Rebate exposure if Law changes.
- Competitive response-price war with Glaxo
- PR issues- Multiple retail prices on same material made on same equipment by same company

Conclusion

Based on the economic and strategic analyses, we conclude that it is necessary for Schering to prepare to enter the market with a generic Proventil Inhaler. We also conclude that it is critically important that we delay the launch of the generic until 60 days before the entry of another generic competitor. Analysis has indicated that too early of an entry unnecessarily sacrifices branded revenue, too late of an entry would cause us to lose generic market share which is unlikely to ever be regained.

We will take all steps necessary to prepare for a launch of a generic Proventil Inhaler. This would entail manufacturing and stockpiling all the necessary elements of the product and holding final assembly and introduction until 60 days prior to the launch of another generic. The cost of this contingency plan would be approximately $580,000. Actual launch of the product is estimated to cost between $500,000 and $1,000,000.

2. Expansion of Warrick Pharmaceuticals

The vehicle for entry into this marketplace will be a separate entity, Warrick Pharmaceuticals. While internal resources can be used for the initial development of the organization, the operation will have to be kept completely separate. The need for a separate entity has been established in earlier chapters. The need for speed of decision making, flexibility in pricing, focus on a different customer base, low cost manufacturing, and high volume/high quality ANDA's are primary among the reasons. (see Appendix 3 for listing of The Warrick Portfolio).

At the same time, if there is to be any real synergy or competitive advantage created by having a generic subsidiary of a PMA company, the subsidiary must be free to utilize services of the parent when it makes economic and competitive sense to do so. Using those "backroom" services which can be productively used will be a key part of the implementation process.

3. Recruitment of Personnel

The acknowledgment that the generic marketplace operates in a very different manner from the branded pharmaceutical market intimates that to successfully run a generic company will require a different management orientation. Since we do not have personnel with this experience in Schering at the moment, we will have to recruit from the outside.

4. Product Portfolio

As indicated in the previous chapter, there will be three primary sources of products feeding into the product portfolio of Warrick Pharmaceuticals:

- Our products going off patent
- Products already off patent, ours and others
- Other's products going off patent

Figure 28
Schering Products Subject to Future Generic Competition

Name	Year Off Patent
Proventil (Inhaler)	Off (1989)
Normodyne	1998
Lotrisone	1998
Vanceril	1999

As Figure 28 indicates, we will have several important products going off patent over the next several years. Generic versions of these products will be marketed by Warrick as they are subjected to generic competition.

A group of our products already off patent (see Chapter V) will also be marketed in generic versions by Warrick. Drugs of other companies already off patent will be examined to see if sufficient value remains to warrant pursuing an ANDA. This may be of interest if there are products with value remaining in areas where we have competitive strength. For example, analyses have shown that topicals are subject to less severe price erosion than pill forms.

In addition, we may develop opportunities to bring to market generic versions of drugs coming off patent on behalf of other PMA companies. These opportunities will only become available to us if we demonstrate the ability to do a superior job with our own products.

The last potential source of products for the portfolio is through the acquisition of a small privately held generic company with a desirable portfolio of ANDA's in hand. As indicated earlier, publicly traded generic companies are currently at multiples which render them unattractive. It is possible, although by no means certain, that over the next year or so a private company may become available at a price which would make sense for Schering.

B. Seek to create leverage for our managed care business.

Another primary objective is to leverage up our branded products within the managed care segment of our business.

Managed Care Value Strategy

The current managed care marketplace is growing with current estimates that 45-50% of Americans participate in some form of managed care. However, in this segment only 20% have a paid drug benefit.

The drug benefits in managed care are generally provided through retail pharmacies with only 20% of drugs dispensed in controlled environments such as staff model HMO's, mail order or hospitals.

Figure 29
Where Is Managed Care Leverage Possible?

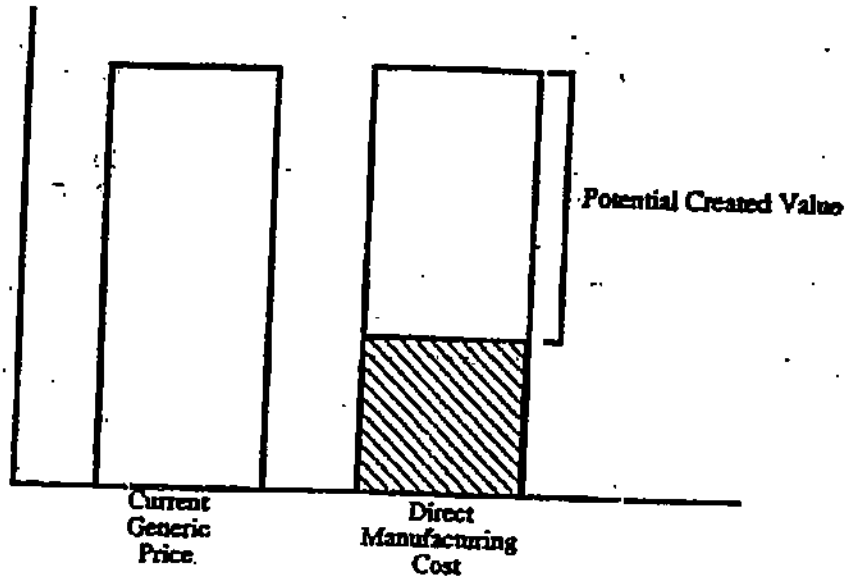
Controllable (Managed Care Entities that take Possession of Drugs)	Non-Controlable (Managed Care Entities that contract for Pharmacy Services)
Staff Model HMOs Hospitals (but not GPOs) Nursing Home Providers Clinics Military Customers Mail Order Pharmacy	IPA HMOs Pharmacy Management Organizations Third Party Administrators Paid Provider Orgs. Indemnity Insurers Employers Medicaid State Assistance Programs Medicare

This reliance by managed care upon retail pharmacy requires a generic strategy to include, at a minimum, chain distribution. Our strategy is to use the future multisource products in the Warrick portfolio to leverage our total brand line.

Using the gap between our manufacturing cost and the generic "retail" acquisition price we will seek to provide value to the leveraged managed

care buyers. To date this has not been successfully achieved in the marketplace. However, as managed care expands and point of purchase computer controls are strengthened we want to be positioned to create marketplace advantages. See Figure 30.

Figure 30
Potential Value to Managed Care



This strategy can not succeed today because generics are not usually contracted for by managed care pharmacy management organizations. They allow chain stores and independent retailers to select the product and the managed care provider caps the cost via a MAC (Maximum Allowable Cost). The pharmacy then searches for the lowest price under the MAC. This is in contrast to the innovator brand product's maximum allowable costs which are usually reimbursed at the AWP price minus 10% plus a $2-3 "dispensing" fee. We currently participate at this level by gaining formulary acceptance and market share in specific systems by providing contracted discounts and "bundles".

The life cycle of the value of our generics to managed care may be short as historically the gap between manufacturing cost and selling price erodes as prices fall with succeeding numbers of generic entrants. Thus new ANDAs

and generic products must continually be introduced and strategic pharmacy distributors maintained to achieve sustained leverage. Please refer to Appendix 5 for a list of major products going off patent in the years between 1993 and 1998.

Each of the products coming off patent will be examined to determine our ability to manufacture them at a reasonable cost and to be in the market soon after patent expiration. We will seek a sufficiently broad product line to gain distribution with the pharmacy chains. It is only after we have established that distribution that we will be able to offer value to Managed Care through bundles of our branded and generic products. See Appendix 1 for an estimate of the market value of managed care leverage.

5. Regulatory, ANDA Process

To gain access to products coming off patent or already off patent, Warrick will need to file a substantial number of high quality ANDA's. This process and the relationship needed with the FDA is significantly different than the NDA process. To do this well will require dedicated resources on both the developmental and regulatory fronts. While we will need to build a dedicated staff to handle the expected volume of ANDA's, the personnel "gap" will be bridged by contracting for these services with outside experienced firms.

A review of Schering's portfolio of products already off patent indicates a number of other products available as candidates for inclusion in the Warrick product portfolio.

6. Manufacturing

Low cost, flexible manufacturing is a key element of this strategy. It is assumed that for current Schering products existing manufacturing lines would be utilized. It is also assumed that products would be transferred to Warrick at direct cost. With the growth of products being developed for new generic manufacture, it will be important to assure that we are capable of producing these products at low cost with high quality.

7. Organizational Design

We recommend that Warrick report into the President of Schering Laboratories. The organization will number around 15 persons. The initial tasks for Warrick will be to identify and develop products for which we would have a competitive advantage. The filing of ANDA's will follow immediately, and within the next year another group of products will be selected to go through the same process.

Summary

Our Generic Strategy can best be summed up as follows:

- Aggressive defense of branded products
- First to market with our own "generic products" (private label versions of our branded products) when generic competition is inevitable
- Build up Warrick Pharmaceuticals as our generic vehicle utilizing generic versions of our own off patent drugs initially
- Develop a portfolio of generics coming off patent sufficient to create the "strategic mass" necessary to get chain distribution for our generic line
- Utilize the broad distribution of our generic line to create "value integrations" of our branded and generic products for the Managed Care segment

Appendix

Appendices

Appendix 1
Leveraging Managed Care

MANAGED CARE LEVERAGE POTENTIAL

During our review of leverage options, we evaluated three areas that could provide potential value to Managed Care Customers:

1. Existing Schering minor products that could be used immediately as value added bundles to managed care customers.

2. Current high volume non-Schering off patent products with generic competition that we can manufacture and offer as value-added package to managed care customers.

3. Future non-Schering products coming off patent that we can manufacture and develop to create a core of high value added options to offer to managed care customers.

Again, the objective of this strategy is to use value-added promotional generic products to create attractive packages for the managed care customer so we can both maintain/increase prices and expand utilization of our branded products.

1. Existing Schering Products

We reviewed the list of Schering minor products (as described in Chapter V) that currently compete in generic marketplaces. A review of their position and potential sales in these markets is fully described in Appendix 3. Overall, our conclusion was that we begin immediately to private label a significant number of these products under the "Warrick" name and begin to compete as generics where economically feasible. Our review of these products in the contracted managed care marketplaces where we now compete, indicated that these products currently have minimal leveraging value. However, our strategy is to begin to test bundling options to specific controllable customers (i.e., hospitals, staff HMO's, small IPA's and possibly mail order). We intend to package these branded minor products at cost or near cost and leverage price concessions or utilization growth on branded products. Again, we would go initially to closed markets where we can effectively control the distribution, avoid diversion and ensure utilization to guarantee value to the Managed Care customer. The premise is to begin immediately to offer some type of value currently to customers with the intent of increasing the value in the future as our stable of promotional

generics broadens. Co-incidently, we would be creating a partnership with the customer by being their long-term provider of certain generic products while increasing the price/utilization of our branded products.

2. Current High Volume Generics

A list of the top 25 generic drugs, which are currently on the market, were reviewed based on our manufacturing capabilities and the potential market value of each product. Twelve of the highest value products were selected and the direct cost to produce each of the products was developed. It was determined that value (the spread between our direct cost to make and the current market value) existed for 8 of the 12 products. (see Attachment 1)

We then assumed, that again, we could only effectively now go to the controllable Managed Care sectors, which has been estimated to be about 20% of the total market. Therefore, our current maximum leverage value was estimated to be $22 million.

Knowing that the time frame to develop ANDA's is at best, 18-24 months and the cost per ANDA is about $5-800,000, we could not economically justify pursuing these products. Specifically, a $4-6 million investment over the next two years would yield very limited leverage value in the future, particularly, with the increased price erosion that these products can continue to expect.

Therefore, our recommendation is to not pursue a strategy of developing or acquiring a stable of current generic products to be used for potential Managed Care leveraging.

3. Future Products Coming Off Patent

Looking to the future and considering the lead time to obtain ANDA's, we identified all major products coming off patent in 1995-1998. These products were then reviewed, and based on our ability to manufacture and adequate ANDA lead times, we selected 10 products with the highest sales value and calculated the maximum potential value in all sectors of the marketplace. (see Attachment 2) We then determined the potential market value of these products considering price brand increases 4% per year and the projected multiple generic drug impact from historical models as

follows:

- Unit Volume assumes 4% generic erosion per month reaching 50% by the 12th month, 60% by the 24th month and 70% by the 36th month.

- Price
  - Branded price remains at 100%.
  - Generic price at 35% of branded price in the first month of introduction declining to 65% by the 12th month, 75% by the 24th month and 85% by the 36th month.

The estimated potential market value was determined to be approximately $2 billion in 1996 and each year beyond.

We then evaluated the potential value to the Managed Care market based on our ability to compete in the "controlled" segment (i.e., Staff Model HMO's and hospitals) which resulted in a market value of approximately $150 million in each of the three years 1996-1998. (This market estimate is considerably less than the 20% previously used because we assumed that these customers already obtain a larger portion of these products either at a discount or through lower cost generics.)

We targeted an aggressive penetration rate of 50% into these markets and therefore felt we could obtain leverage value at about $65-85 million each year over the three year period. Assuming we could only retain (swap) about half of this leverage value through higher prices or expanded utilization on our branded products, we then adjusted this profit retention by the generic product's cost of goods (estimated at 20% of Managed Care leverage value). The net result is that we believe there is $20-25 million in net value per year in the closed Managed Care markets alone. This more than offsets the ANDA investment costs, ($5-8 million), and the annual operating costs ($1-2 million) of Warrick Pharmaceutical. (See Attachment 3 for potential value over the 1996 to 1998 timeframe.)

We must also discuss the potential future upside of Managed Care leveraging in the non-controlled markets (i.e., IPA's, PPO's, PMO's). With a solid core of replenishable promotional generics, combined with the expected alignment, consolidation and information access of these major players, we feel we can offer value and obtain significant leverage here as

well. If we simply assume that these customers grow to 20% of the overall market by 1996 and apply the similar rationale as for the closed markets, we could have a minimum upside potential of another $30-40 million a year. Finally, this does not even consider the fact that if we have a viable group of early entry "promotional" generics, we may be able to effectively compete in the overall retail generic market as well.

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